Smart Medication Delivery Systems:
Infusion Pumps

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April, 2009
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Executive Summary

Background

Medication errors are the most significant cause of medical injuries, representing 19.4% of all adverse events. Intravenous (IV) infusions have been identified as frequent contributors to medication errors, and the injuries that result from them. General infusion pumps were designed to improve accuracy and continuity of IV infusions by allowing nurses to program an hourly rate and volume. However, studies have shown that these devices are involved in 35-60% of the estimated 770,000 Adverse Drug Events (ADEs) that occur each year. Most ADEs associated with IV infusion devices occur as a result of nurses manually inputting incorrect settings into the pump. The most common infusion errors include unit errors, multiple of ten errors, miscalculations and push-button mistakes.

For example, fatal errors have occurred as a result of decimal entry errors when programming infusion pumps (e.g., programming morphine at 90 ml/hr instead of 9.0 ml/hr, causing a 10 fold overdose). Thus, although infusion pumps have revolutionized the way nurses deliver intravenous therapy, they have also led to ADEs.

In an attempt to reduce infusion errors, manufacturers have developed pumps that have Dose Error Reduction Systems (DERS), which include hospital-defined drug libraries with dosing limits and other clinical advisories integrated into the system (i.e., smart pumps). Smart pumps, particularly those with bar code readers, are assumed to simplify aspects of the drug administration process. However, smart infusion systems (with or without bar coding) may add to the demands of the overall drug administration process or, in some cases, introduce completely new tasks (e.g., select the clinical care area, select drug name and concentration, or scan bar code on iv label) that may cause nurses to make new types of errors (e.g., select the incorrect drug concentration).

Traditionally, the process for implementing standard intravenous pump technology was straightforward as it had little impact on the rest of the medication delivery process. That is, the implementation process consisted primarily of placing the chosen product into a specific environment and training nurses on the technical aspects of the pump. The implementation process for smart pump technology, however, is more complex as it requires a larger coordinated effort with stakeholders involved throughout the medication process.

The Ministry of Health and Long-Term Care of Ontario (MoHLTC) and the Ontario Health Technology Advisory Committee (OHTAC) engaged the University Health Network’s (UHN) Healthcare Human Factors Group (HHFG) to collect evidence on the effectiveness, and safety of smart infusion systems. To this end, HHFG conducted both lab and field evaluations.

This report assesses the impact of different types of infusion technologies (i.e., traditional pumps vs. smart pumps vs. smart pumps with bar coding) on existing clinical practice, and the current state of smart pump adoption in Ontario. Furthermore, this report
identifies key recommendations to successful migration from traditional pumps to smart infusion systems. The Healthcare Human Factors Group’s overall assessment, key findings, and recommendations are summarized below with additional detail in subsequent chapters of this report.

**Overall Assessment**

As a patient safety initiative, effective use of smart pump technology is dependent not only on the design of the pump itself but also on the way it is implemented at the institution. Most Ontario healthcare facilities that are migrating from traditional pumps to smart pump systems are unaware of the need for a different implementation process, and therefore, are failing to deploy an integrated system.

Major improvements in a number of core areas are required before Ontario hospitals can be assured that investments in smart pump systems are providing value-for-money, by significantly advancing the institution’s patient safety agenda.

The Healthcare Human Factors Group’s assessment has concluded that smart pump systems can, and should, play a significant role in hospitals’ patient safety agenda. Nurses, pharmacists and many stakeholders throughout the medication administration process have crucial roles to play in ensuring the success of smart pump systems. Given the promise that a fully integrated medication administration process holds, healthcare institutions view smart pumps as a key enabler for their patient safety initiatives. A well thought out project charter, clarity of direction, and buy-in from all major stakeholders will be required to address our key findings and recommendations.

**Key Findings**

- Thirteen percent of Ontario hospitals currently use smart pumps and another 6% are in the process of implementing smart pumps. Thus, adoption rate of smart large volumetric infusion pumps in Ontario has been low.

- Sixty-eight percent of Ontario hospitals that were interviewed did not ensure wireless connectivity prior to implementing smart pumps.

- Although 47% of hospitals that were interviewed had wireless infrastructure, 16% of them did not purchase pumps with secure wireless capability. These results suggest that many Ontario institutions are treating deployment of smart pumps as they would a traditional infusion pump. Accordingly, they are not setting themselves up to reap the benefits that smart pumps can offer.

- Twenty-three percent of Ontario hospitals that were interviewed proceeded with their smart pump implementation, without establishing a complete list of standardized concentrations. Standardization of drug concentrations, however, is critical to ensuring (a) synchronicity between physician orders and smart pumps, and (b) compliance with use of the Dose Error Reduction System (DERS).
• Soft limits (that can be overridden) in smart infusion pumps had no significant effect in preventing errors. Sixty-seven percent of Ontario smart pump users that were interviewed reported having a high rate of soft limit overrides. That is, most institutions reported that nurses often ignore and override soft limit alerts. Thus, although smart pumps alert users as to soft and hard limit overdose errors, users often do not respond to these alerts in a safe manner.

• Hard (unchangeable) limits prevented dosing errors, thereby increasing patient safety. When faced with hard limit warnings, which do not allow nurses to override but rather force the re-programming of the pump setting, nurses do indeed respond in a safe manner. However, most Ontario smart pump users (i.e., 62%) that were interviewed do not implement hard limits, or only implement a few. Respondents stated that the main reason for not implementing hard limits was that they are too difficult to set given the wide dosage range required for certain drugs. By not implementing hard limits, many smart pump users are evading the software dosing safeguards that make pumps smart, consequently reducing the benefits of having a drug library.

• Until barcode pumps are integrated with other systems within the medication administration process, their role in enhancing patient safety will be limited. Barcode pumps are susceptible to many of the same errors (e.g., wrong drug errors) as other types of pumps.

• Further improvements to pump technologies are needed to mitigate risks associated with IV infusions, particularly secondary infusions.

**Recommendations**

Smart pump system implementation must be viewed and approached as a patient safety initiative, rather than a pump replacement initiative. To this end, the top five recommendations for successful smart pump implementation are outlined below.

1. **Establish standardized concentrations and dosing units** prior to smart pump implementation, to ensure Return On Investment (ROI).

2. **Select a pump design that encourages entry into the Dose Error Reduction System (DERS)**, and mandate the use of DERS. If not, nurses will bypass the safety features of the pump by programming in the generic mode, thereby leading to a negative ROI.

3. **Make every effort to implement a wireless networked environment** as it is necessary for frequent drug library updates and for continuous quality improvement.

4. **Prepare nurses for the cultural shift of having to think in terms of dose rate instead of a flow rate.** That is, prior to introduction of infusion pumps, nurses would hang the intravenous (IV) medication bag and count the drip rate (i.e., ml/hr). With the creation of traditional IV pumps, this practice remained, as
nurses were required to enter the flow rate and volume to be infused. Given that physician orders for continuous infusions are typically provided in dose rate (e.g., mg/hr), nurses would convert the dose rate into a flow rate prior to programming the pump. With smart pumps, however, nurses are provided with the option of entering the flow rate or the dose rate. Institutions should encourage the entry of dose rate, as it reduces the need for error-prone mathematical conversions.

5. **When selecting a smart pump, assess how readily Bar Coded Medication Administration (BCMA), and Positive Patient Identification (PPID) could be added to the pump system** to ensure future seamless integration.
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<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>ADE</td>
<td>Adverse Drug Events</td>
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<tr>
<td>ASHP</td>
<td>American Society of Health-System Pharmacists</td>
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<td>BCMA</td>
<td>Bar Code Medication Administration</td>
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<td>BPOC</td>
<td>Bar Code Point of Care</td>
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<td>CCA</td>
<td>Clinical Care Area</td>
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<td>CPOE</td>
<td>Computerized Physician Order Entry</td>
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<td>CQI</td>
<td>Continuous Quality Improvement</td>
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<td>DERS</td>
<td>Dose Error Reduction System</td>
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<td>eMAR</td>
<td>electronic Medication Administration Records</td>
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<td>FMEA</td>
<td>Failure Modes and Effects Analysis</td>
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<tr>
<td>GTA</td>
<td>Greater Toronto Area</td>
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<td>HHFG</td>
<td>Healthcare Human Factors Group</td>
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<td>ISMP</td>
<td>The Institute for Safe Medication Practices</td>
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<td>ISMP Canada</td>
<td>The Institute for Safe Medication Practices Canada</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>IV</td>
<td>Intravenous</td>
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<td>MAS</td>
<td>Medical Advisory Secretariat</td>
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<td>MoHLTC</td>
<td>The Ministry of Health and Long-Term Care of Ontario</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<td>OHTAC</td>
<td>Ontario Health Technology Advisory Committee</td>
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<td>PCA</td>
<td>Patient-Controlled Anesthesia</td>
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<td>PPID</td>
<td>Positive Patient Identification</td>
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<td>REB</td>
<td>Research Ethics Board</td>
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<td>RFID</td>
<td>Radio Frequency Identification</td>
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<td>RFP</td>
<td>Request for Proposal</td>
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<td>ROI</td>
<td>Return On Investment</td>
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<td>UHN</td>
<td>University Health Network</td>
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<td>UNA</td>
<td>User Needs Assessment</td>
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Acknowledgments

The authors gratefully acknowledge the Ministry of Health and Long-Term Care of Ontario (MoHLTC), particularly Dr. Leslie Levin and Dr. Birthe Jorgensen of the Medical Advisory Secretariat (MAS), and the members of the Ontario Health Technology Advisory Committee (OHTAC) for supporting this work. We also acknowledge the involvement of the hospital staff at the University Health Network (UHN). The authors thank Ms. Eliza To for her help with the pharmacy requirements of this project and for her valuable insights. We would especially like to thank Sonia Pinkney, Mark Fan, and Sarah Rothwell for their help in the execution of the project.
1 Introduction

1.1 Issue and Motivation for Research

“Smart” infusion pumps have the potential to improve the safety of delivering medications. However, despite a cost of three to four times more than traditional pumps, achieving the safety benefits of smart pumps has been difficult. To address this problem, the Ontario Ministry of Health and Long Term Care (MoHLTC) and OHTAC commissioned the University Health Network’s (UHN’s) Healthcare Human Factors Group to: (a) collect evidence on the potential safety benefits of smart infusion pumps, (b) measure adoption rate of smart pump systems by Ontario hospitals, and (c) develop strategies for Ontario hospitals to improve implementation of smart pump systems.

1.2 Goals

The three main goals of this project were as follows:

- To assess the impact of the different types of large volumetric IV pumps (traditional pump, smart pump, and smart pump with bar coding) on nurses’ ability to safely and efficiently administer IV medications.
- To gather accurate information on current levels of adoption of large volumetric smart infusion pumps in Ontario hospitals, and identify the associated migration processes.
- To provide recommendations to help guide other hospitals in their future migration endeavours.

These three goals are respectively addressed in the following sections of the report: (1) lab study results, (2) field study results: current state of smart pump adoption in Ontario, and (3) roadmap to recommended migration process.

The report answers the following questions:

- What are the risks associated with IV infusions and to what extent do different pump technologies (i.e., traditional, smart pump, and smart pump with bar coding) mitigate these risks?
- What is the adoption rate of smart pump systems by Ontario hospitals?
- What processes have hospitals employed when migrating from traditional to smart infusion systems, and what were the barriers to complete optimization?
- What are recommended practices for selecting and implementing smart infusion systems in Ontario hospitals?

1.3 Scope

The following are excluded from the scope of this paper:
• Examination of patient-controlled anesthesia, enteral feeding, ambulatory or syringe pumps
• Creation of a recommended drug library (e.g., nomenclature, standard concentrations, limits)
• Side by side comparison of vendor products
2 Background

A comprehensive literature search was completed to identify, appraise, select and synthesize all high quality research evidence relevant to understanding the following:

1. Role of smart infusion systems in medication error prevention
2. Smart pumps’ Dose Error Reduction System (DERS)
3. Implementation and integration of smart pump systems within the medication administration process

The electronic databases searched included MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, All EBM Reviews (Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA and NHSEED), IngentaConnect, CINAHL, Pre-CINAHL, EMBASE, Health Business Fulltext Elite, INAHTA and Ovid Nursing Database. The keywords used for the search included smart pump, smart infusion, infusion pump, adverse drug events, medication error prevention. As well, the websites of the Institute for Safe Medication Practices (ISMP) and the Institute for Safe Medication Practices Canada (ISMP Canada) were searched both manually and using the Google search engine. The title and abstract (if available) of each article were reviewed for relevance, and the full articles of the relevant studies were obtained. The bibliographic references of the selected articles were also reviewed, and the full articles were obtained as necessary. The search was conducted from December 19, 2007 to January 15, 2009 and resulted in 239 relevant articles.

The inclusion criteria were as follows:
- Publications in English
- Studies related to IV infusions
- Peer-reviewed or grey literature

The exclusion criterion was as follows:
- Studies on smart pumps for patient-controlled anesthesia (PCA) or epidural infusions

2.1 Role of Smart Infusion Systems in Medication Error Prevention

Medication errors are the most significant cause of medical injuries, representing 19.4% of all adverse events. It is estimated that the annual costs of Adverse Drug Events (ADEs) is $2.8 million US (for a 700-bed teaching hospital), leading to massive cost liabilities given the expansive scope of current health care practices. While Canadian data is more limited than that of the United States, there are indicators of the incidence and severity of adverse drug events in Canada. The research on incidence rates of adverse events in Canadian hospitals by Baker, Norton et al. indicated that approximately 185,000 admissions per year are linked to an adverse event, and that nearly 70,000 of these may be avoidable. International survey results from 2005 show that approximately 10% of sicker Canadian adults (meeting certain criteria pertaining to recent illnesses, disabilities or intensive medical care), received a wrong medication or dose in the previous two years. Furthermore, in response to medication errors occurring most
frequently during patient care transfers, there are Canadian healthcare safety initiatives that list adverse drug events as a specific problem to address. Thus, there is a growing evidence and awareness of the need to prevent medication errors.

Medication errors can be made at various stages throughout the medication process. Specifically, medication errors can occur at the ordering, prescribing, transcribing, dispensing, and/or administration stages of the medication process. The safety impact of medication errors may vary depending on the stage of the process at which the error occurs. For example, if errors occur at the medication prescribing, transcribing or dispensing stages, healthcare providers may notice and correct the mistake before it reaches the patient. If, however, the error occurs at the administration stage and reaches the patient, there may be no chance of recovering from the error. Researchers have found that most errors occur during prescribing and administering of medications and that the most harmful errors occur during administration. A landmark 1995 study by Bates showed that analgesics accounted for 30% of all adverse drug events, and that administering the wrong dose was the most common error, followed by wrong drug. Thus, the administration stage is a high-risk procedure, and is an area of opportunity to enhance patient safety by focusing on error prevention interventions, particularly with high-alert medications.

Intravenous (IV) infusions have been identified as frequent contributors to medication errors, and the injuries that result from them. This is not surprising given that approximately 90% of patients receive medications via the IV route, and IV pumps are responsible for the majority of medication deliveries. Health Canada reported that between 1987 and March 2003, 425 separate incidents involving infusion pumps were reported, 23 resulting in death, 135 in injury, and 127 having the potential to lead to death or injury. Thus, IV medication errors present a particularly challenging problem.

General infusion pumps were designed to improve accuracy and continuity of IV infusions by allowing nurses to program an hourly rate and volume. However, studies have shown that these devices are involved in 35-60% of the estimated 770,000 Adverse Drug Events (ADEs) that occur each year in the US. Most ADEs associated with IV infusion devices occur as a result of nurses manually inputting incorrect settings into the pump. More specifically, the Institute of Medicine estimated that two-thirds of preventable deaths are due to infusion therapy and are attributable to manual programming errors when using infusion pumps. The most common infusion errors include unit errors, multiple of ten errors, miscalculations and push-button mistakes. For example, fatal errors have occurred as a result of decimal entry errors when programming infusion pumps (e.g., programming morphine at 90 ml/hr instead of 9.0 ml/hr, causing a 10 fold overdose). Another common push-button error is the double key bounce, where a single press of the button is intended, but two inputs are actually received by the device. Thus, although infusion pumps have revolutionized the way nurses deliver intravenous therapy, they have also led to ADEs.

To address high incidence of infusion errors, manufacturers have developed smart pumps. Smart pumps have Dose Error Reduction Systems (DERS), which include
hospital-defined drug libraries with dosing limits and other clinical advisories integrated into the system (i.e., smart pumps). Rather than have nurses work with traditional general-purpose infusion pumps that have a wide range of acceptable programming parameters, smart pumps are designed with drug specific safety software to help nurses detect and correct infusion programming errors (or order errors that originate prior to pump programming). When the dosage parameters are entered, the software checks to ensure the dosage values are within pre-determined dosage ranges set by the institution. If the parameters entered by the nurse match those contained in the pump’s drug library, the pump allows the infusion to begin. If, however, the parameters entered by the nurse exceed the specified limits in the pump’s drug library, the pump will alert the nurse as to which parameter is out of the recommended range. The pump will provide either a “soft” or “hard” limit warning. A soft alarm allows the nurse to override the limit and continue infusing the medication. Conversely, a “hard” limit requires the nurse to re-program the pump with parameters that are within the institution’s specified limits prior to starting the infusion. If nurses program outside of DERS there are no safety features available. This method is called generic programming. Thus, smart pumps provide an extra layer of safety compared to traditional pumps as they contain safeguards against incorrect dosage administration. Smart pumps, however, do not help prevent errors related to administering the right drug, to the right patient, by the right route, at the right time. Smart infusion pumps with bar coding were designed to help prevent these latter types of errors.

Smart pumps, particularly those with bar code readers, are assumed to simplify aspects of the drug administration process. However, smart infusion systems (with or without bar coding) may add to the demands of the overall drug administration process or, in some cases, introduce completely new tasks (e.g., select the clinical care area, select drug name and concentration, or scan bar code on iv label) that may cause nurses to make new types of errors (e.g., select the incorrect drug concentration). In 2002, 161 smart infusion device-related incidents (from 18 trusts) were reported to the National Health Service’s (NHS) National Patient Safety Agency during a nine-month audit of errors and near misses in the NHS. The National Patient Safety Agency attributed these infusion pump errors to rapid technological advances and the emergence of highly variable and complex infusion devices that make it difficult for (a) nurses to stay up to date with the devices and (b) staff to correctly maintain and update the devices. Furthermore, researchers have questioned the risk/benefit tradeoff associated with soft limits found on smart pumps. That is, although soft limits provide more flexibility than hard limits by allowing nurses to bypass warning alerts, they can also circumvent the purpose of a smart pump by permitting nurses to deliver drugs outside of preset drug safety limits. Given that medication administration is a high-risk activity, there is a need to understand how to integrate smart infusion systems (with or without bar coding) into work processes such that the frequency of drug administration errors is reduced without confusing nurses or overloading their cognitive capabilities.

Researchers have explored the benefits of using smart pumps compared to traditional pumps to administer medication. Outcomes, however, have been mixed. Although some studies have found that smart pumps reduce errors compared to traditional pumps,
others have shown that smart pumps do not reduce the frequency of programming errors compared to traditional pumps and can even introduce new types of errors. This past research, however, has important limitations. Several prospective studies assessed the potential impact of smart infusion devices on medication errors. These studies, however, did not explicitly evaluate whether the identification of errors was due to smart pump technology or whether errors may have been detected and remedied with traditional pump technology; thus making it difficult to draw conclusions regarding the impact of smart pumps on patient safety. Other researchers derived data from hospital based incident reporting systems to evaluate the types of IV pump errors. These results, however, are not adequately quantifiable due to underreporting. To date, there has been no study that has empirically tested the effects of pump technology on safe medication administration by conducting a controlled experiment in which types of pump technology are compared.

In sum, intravenous (IV) administration errors present a serious problem for hospitals as they are associated with the most critical adverse drug events. Traditional, general-purpose infusions devices cannot limit doses or be readily customized for patient or treatment specific populations. Smart infusion systems have been developed to enhance patient safety by reducing the potential for IV medication errors. Although results of studies that have compared the benefits of traditional versus smart pump systems have been mixed, there is a general consensus that effective use of pump technology is dependent not only on the design of the pump itself but also on the way it is implemented at the institution. The ensuing sections provide a description of (1) smart pumps’ Dose Error Reduction System (DERS), and (2) the implementation and integration of smart pump systems within the medication administration process.

2.2 Description of Smart Pumps’ Dose Error Reduction System

Smart pumps have a medication safety system referred to as a Dose Error Reduction System (DERS). A DERS is designed by the manufacturers and contains software that helps alert users to potential dose errors prior to medication delivery. Specifically, smart pumps allow hospitals to configure the software to specific characteristics of either a patient type (e.g., adult or pediatric) or treatment type (e.g., oncology or medical surgery). Based on the patient or treatment type selected, hospitals can customize a library of drugs, concentrations, dosing units and dosing limits to meet the needs of the specific user group or clinical care area. At the bedside, the nurse will program a smart pump by first selecting either a patient or treatment type and then selecting the drug and concentration, followed by entering dosage parameters. Therefore, a single pump can be applicable to a variety of different clinical wards.

At the point of administration, the nurse will program a smart pump by first selecting either a patient or treatment type and then selecting the drug and concentration, followed by entering dosage parameters. When the dosage parameters are entered, the software checks to ensure the dosage values are within pre-determined dosage ranges set by the institution. If the dosage value is outside of the acceptable dosage limits, a limit alert will be displayed to the nurse on the screen of the pump. Depending on the dosage range, the nurse will receive either
A soft or hard limit alert will allow the nurse to override the warning and administer the fluid as is, whereas a hard limit will not allow the nurse to administer the fluid under its present dosage values.

Figure 1 below provides a general overview of the workflow for programming a smart pump. The user will program a smart pump by first selecting the Clinical Care Area (CCA) and entering into DERS. The user will then select the drug name and concentration and enter the dosage parameters before starting the infusion. The order of the programming subtasks can differ between smart pump models, however the tasks performed during programming are the same. The programming subtasks of multi-channel pumps depend on whether the user is programming the first infusion on the smart pump or programming an infusion after the first infusion is running. Typically, if the user is programming the first channel s/he must turn on the pump, select new/old patient, select CCA and enter DERS before programming the IV order. If the user is programming an infusion after an infusion is running on the first channel, the user is only required to enter DERS before starting to program the IV order. To incorporate all programming subtasks, the workflow in Figure 1 is reflective of a user programming an infusion on the first channel.
Smart pumps store alert and event log information that results from clinical use of drug libraries, allowing hospitals to (a) mine the data for insight into their medication practices, and (b) improve the drug libraries and clinical practice. Rich details regarding medication administration can be extracted such as drug protocol use, reprogramming events, actions after reprogramming, number of warnings, number of warning overrides, drugs most frequently associated with reprogramming, and clinical units with highest warning overrides, all with timestamps. For example, Fanikos et al. found data indicating high levels of reprogramming corresponded with the nursing shift change schedule between 2 and 4pm. Therefore, by analyzing trends for root causes, underlying system issues can be probed or explored to generate insightful and effective policy decisions surrounding the medication order process or patient handover. It has been highly recommended, however, that wireless infrastructures be used to enhance a hospital’s ability to update and maintain smart pumps’ drug libraries and to download log data. If wireless transfer in unavailable, drug library uploads and log data downloads would require physically locating and interacting with all pumps. Therefore, from a
quality perspective, smart pumps offer themselves as an exceptional tool for capturing adverse event data with their logging features, especially when used in tandem with a wireless infrastructure.

### 2.3 Migration from Traditional Pumps to Smart Pump Systems

#### 2.3.1 Requires a complex implementation process

Traditionally, the process for implementing standard intravenous pump technology was straightforward as it had little impact on the rest of the medication delivery process. That is, the implementation process consisted primarily of placing the chosen product into a specific environment and training nurses on the technical aspects of the pump. The implementation process for smart pump technology, however, is more complex as it requires a larger coordinated effort with stakeholders involved throughout the medication process. For example, implementation of traditional IV infusion systems did not involve development of drug libraries or connectivity to wireless servers, therefore, involvement of pharmacy and IT was not pivotal to the process. Implementation of smart infusion pump systems, however, requires a formal process which involves many stakeholders, and should not be viewed as a pump replacement initiative but rather as a patient safety initiative.

Migrating from traditional IV infusion pumps to smart infusion pump systems involves much more than simply replacing the pump. Smart pumps have been designed to reduce dosing errors when administering intravenous IV medications. Specifically, smart pumps use hospital-specific drug libraries to set upper and lower dosing limits for the drug being administered. Alerts can be programmed to warn nurses if they enter a parameter that (a) exceeds a soft limit that allows them to override the limit, or (b) a hard limit that forces nurses to reprogram or bypass the drug library. Furthermore, smart infusion systems can provide Continuous Quality Improvement (CQI) data which can inform hospitals about the frequency of use and effectiveness of their systems. Therefore, the CQI system can help identify improvements required to reduce errors. As with other information technologies that were designed to help prevent medication errors (e.g., computerized physician order entry, and automated dispensing devices), smart infusion pump systems must be integrated within the rest of the medication administration process to ensure its success and optimization. Thus, the ultimate goal is not to implement stand-alone “smart IV pumps”, but rather to implement a “smart IV system” that integrates infusion pumps with other information systems.

It is essential to identify at the outset the impact that smart infusion pump systems can have on the various stages and stakeholders involved in the medication administration process. For example, smart infusion systems will have their greatest impact if they help link pieces of information (e.g., information contained within physician orders and drug libraries) and if they alleviate repetitive tasks (e.g., checks for problems). Smart infusion pump systems can improve the medication administration process by harnessing the strengths of information technology (e.g., remembering what rules apply for dosing limits) and freeing up clinicians’ cognitive resources to allow them
to do what they do best (e.g., think critically about whether other treatments are needed).

2.3.2 Requires integration within the medication administration process

Smart infusion pump systems have the potential to improve medication administration safety. It has been estimated that the adoption rates of smart pump systems in the United States is as high as 44%. To date, however, there have been no studies that provide reliable estimates of the adoption of smart pumps by Canadian hospitals. Some healthcare researchers feel that smart pump technology has not lived up to expectations because IV medication error rates have not decreased to a level where the benefit of the technology significantly outweighs its cost. Most healthcare facilities have chosen to implement smart pumps as a stand-alone system instead of integrating smart pumps with other clinical information systems such as Computerized Physician Order Entry (CPOE), Pharmacy Information System (PhIS), Bar-Coded Medication Administration (BCMA) and electronic medication administration records (eMAR). This fragmented approach severely limits the ability of smart pumps to intercept medication errors because it can only intercept wrong dose errors, omitting wrong patient, drug name, time errors, and route errors. This limitation has been observed by Nuckols et al. who analyzed medical records from 4604 patients with 20,559 bed-days in Intensive Care Units (ICUs) and found that only 4% of medication errors could have been intercepted by a smart pump. Thus, rather than having the continuity that is needed in realizing a complete medication delivery system, manufacturers produce and healthcare organizations deploy a number of technologies, such as smart pumps, that are often not interoperable and that do not facilitate a single overarching purpose.

The technologies available to create an integrated system revolve around standardized concentrations and dosage units, bar coding, wireless networking, Radio Frequency Identification (RFID), Computerized Physician Order Entry (CPOE), and electronic medical administration records (eMARs). Clinical practice will always be somewhat variable given the inherent variability in patient needs. However, it is crucial to reduce unnecessary variability in drug concentrations and dosing units as it increases opportunities for error. Bar code medication administration (BCMA), or Bar Code Point of Care (BPOC), may require three entities to be scanned at the time of medication delivery: the patient armband, a clinician’s identification badge, and the drug packaging. These three pieces of information are input into the pump immediately before delivery so that the pump cannot be programmed for the wrong drug, be assigned to the wrong patient, or be administered by anyone other than a clinician with the right access level. Radio Frequency Identification (RFID) has also been proposed instead of bar codes for patient or clinician identification. While RFID tags may cost much more than bar codes, they do not require line of sight to read, can scan multiple tags at once, and can both read and write. In addition, they are reusable, more durable and more accurate. Since unit dose drug packages move through the medication cycle in large volumes, the tags associated with RFID would likely be used for patient and clinician identification while bar codes remain in use for medication. One of the advantages of RFID is that it can be read without disturbing the patient because proximity to the RFID tag alone will be sufficient to read the necessary information.
The addition of wireless networking to administration workflow can add further value and safety features to the process. First, physician’s orders can be transmitted to a device server after being approved by pharmacy. At the time of administration, when the medication bar code is scanned, it is matched with the order on the server, and populates the pumps parameters according to the physician’s orders stored on the server. At this point, the nurse simply reviews the pump settings and starts the infusion. The automated system is capable of transmitting the infusion with the associated clinician and patient ID for eMAR and other documentation. Although integration of smart pumps with other technology systems greatly enhances the effectiveness of the smart pumps, smart pumps are of great value even if not wireless or bar code enabled, because they reduce errors related to programming/delivering the wrong dosing unit and/or the wrong drug dose rate. Thus, at the very least, hospitals must invest sufficient time and effort into (1) establishing standardized concentrations and dosing units, and (2) developing complete drug libraries to ensure that clinicians have the proper tools at their disposal to effectively use the smart pump technology.

2.4 Current State of Smart Pump Adoption in Ontario

2.4.1 Adoption rate of Ontario hospitals that currently use, or are in the process of implementing smart pumps

Overall, 13% of Ontario hospitals use smart pumps and another 6% are in the process of implementing smart pumps (see Table 1). Hospitals with fewer than 100 beds were least likely to have smart infusion pumps (see table 2).

<table>
<thead>
<tr>
<th>Status</th>
<th>Total</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently Implemented</td>
<td>20</td>
<td>13.2%</td>
</tr>
<tr>
<td>In process</td>
<td>9</td>
<td>5.9%</td>
</tr>
<tr>
<td>No smart pumps</td>
<td>123</td>
<td>80.9%</td>
</tr>
</tbody>
</table>

Table 1: Smart pump adoption in Ontario

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Large (&gt;100 beds)</th>
<th>Small (&lt;100 beds)</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>10</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Teaching</td>
<td>9</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Grand Total</td>
<td>19</td>
<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 2: Smart pump adoption in Ontario as a function of hospital type and size

2.4.2 Licensed smart pump products in Canada

Table 3 below provides a list of the 8 licensed smart pump products in Canada.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Date device licensed in Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal Health</td>
<td>ALARIS SE SINGLE/DUAL CHANNEL VOLUMETRIC INFUSION PUMP WITH GUARD RAILS</td>
<td>September 22, 1999</td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>ALARIS PATIENT CARE SYSTEM</td>
<td>September 22, 1999</td>
</tr>
<tr>
<td>Baxter Healthcare</td>
<td>COLLEAGUE CXE 3-CHANNEL OR 1-CHANNEL VOLUMETRIC INFUSION PUMP</td>
<td>June 12, 2007</td>
</tr>
<tr>
<td>Corporation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospira Inc.</td>
<td>PLUM A+ 3-CHANNEL OR 1-CHANNEL VOLUMETRIC INFUSION PUMP</td>
<td>November 25, 2002</td>
</tr>
<tr>
<td>Hospira Inc.</td>
<td>SYMBIQ INFUSION SYSTEM, 1-CHANNEL OR 2-CHANNEL</td>
<td>March 20, 2007</td>
</tr>
<tr>
<td>BBraun</td>
<td>SPACE INFUSION SYSTEM - INFUSOMAT SPACE VOLUMETRIC INFUSION PUMP</td>
<td>November 23, 2006</td>
</tr>
<tr>
<td>BBraun</td>
<td>OUTLOOK SAFETY INFUSION SYSTEM</td>
<td>February 14, 2002</td>
</tr>
<tr>
<td>Sigma International</td>
<td>SPECTRUM INFUSION PUMP WITH MASTER DRUG LIBRARY</td>
<td>October 21, 2008</td>
</tr>
<tr>
<td><strong>Total number of smart pump products licensed by Health Canada</strong></td>
<td><strong>8</strong></td>
<td><strong>N/A</strong></td>
</tr>
</tbody>
</table>

Table 3: List of the eight licensed smart pump products in Canada (Note: the total number is after considering products of the same product line but with different number of channels as a single product)

### 2.4.3 Market penetration of smart pump systems in Ontario hospitals

As shown in Table 4 below, three major manufacturers (i.e., Baxter, Cardinal, and Hospira) dominate the Ontario health care market for smart pump systems. BBraun manufacturer has a comparatively small market share, and Sigma manufacturer does not yet have any market share, as it has only recently been licensed in Canada.

<table>
<thead>
<tr>
<th>Adoption Status</th>
<th>Vendor</th>
<th>Baxter</th>
<th>Cardinal</th>
<th>Hospira</th>
<th>BBraun</th>
<th>Sigma</th>
<th>Unknown</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>In process</td>
<td></td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Users</td>
<td></td>
<td>8</td>
<td>7</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td>9</td>
<td>8</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>29</td>
</tr>
</tbody>
</table>

Table 4: Market penetration of smart pump systems in Ontario hospitals
2.4.4 Geographic distribution by manufacturer

The following map (see Figure 2) illustrates the geographic distribution of smart pumps by city. Most hospitals that are currently using smart pump systems are in the South-East region of Ontario around the Greater Toronto Area (GTA).

![Map of Ontario showing health care organizations with smart pump systems](http://maps.google.com/)

Figure 2: Ontario map of health care organizations that have purchased smart pump systems from three major vendors. Source: Copyright 2009 Google – Map data

2.4.5 Cost associated with migration from traditional pumps to smart pump systems

In addition to hardware and software costs, smart pump adoption requires a significant time investment both during implementation period and post-implementation for ongoing maintenance and quality improvement. Optimized smart pump adoption requires the dedication and buy-in from staff across the hospital (e.g., nurses, pharmacists, IT, biomedical engineers) as well as the creation, customization and maintenance of drug libraries for different clinical care settings. Therefore, the human resource demands are much higher when implementing smart pumps compared to traditional pumps. Table 5 provides an example of the differences in upfront and ongoing costs associated with adoption of traditional IV infusion pumps versus smart IV infusion pump systems.
<table>
<thead>
<tr>
<th>Item</th>
<th>Traditional</th>
<th>Smart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump units (single channel products)</td>
<td>$600,000 to $900,000</td>
<td>$1,520,000 to $3,220,000</td>
</tr>
<tr>
<td>Wireless infrastructure establishment</td>
<td>N/A</td>
<td>$300,000³</td>
</tr>
<tr>
<td>One-time software licensing fee</td>
<td>N/A</td>
<td>$360,000 to $450,000</td>
</tr>
<tr>
<td>Implementation consulting fee</td>
<td>$7,000</td>
<td>$100,000 to $200,000</td>
</tr>
<tr>
<td>IV tubing sets (price per set)</td>
<td>$3 to $15</td>
<td>$3 to $15</td>
</tr>
<tr>
<td>Annual pump maintenance cost¹</td>
<td>$30,000</td>
<td>$30,000</td>
</tr>
<tr>
<td>Annual software maintenance fee (ongoing licensing, updates, fixes, etc.)</td>
<td>N/A</td>
<td>$20,000 to $40,000</td>
</tr>
<tr>
<td>CQI data analysis consulting fee</td>
<td>N/A</td>
<td>$2,500 per day²</td>
</tr>
</tbody>
</table>

Table 5: Differences in upfront and ongoing costs associated with adoption of traditional IV infusion pumps versus smart IV infusion pump systems (these costs do not include human resource demands which are also higher for smart pump systems compared to traditional pumps).

Notes: The cost estimates for smart infusion systems shown above are based on the following sources:
  a. ECRI Institute’s 2007 report on smart pumps for general infusions
  b. a smart pump vendor that was available to provide approximate cost estimates for the purposes of this study
  c. a few Ontario hospitals that have implemented a smart infusion system for general infusions or PCA infusions and were able to provide their cost estimates

As such, these estimates are not meant to be used for budgeting. Rather, the estimates are provided to highlight the differential costs associated with implementing and using smart infusion systems compared to traditional pumps.

- All estimates are in CAD. When source estimates were in USD, the estimates were adjusted by 25% considering higher prices of biomedical devices in Canada than in the US. Also, a ratio of 1.2 CAD = 1 USD was used for converting the estimates in USD into CAD.
- The estimates are for implementing 300 single-channel pumps at a typical 300-bed hospital with 10 floors (i.e. 30 beds per floor).
- The cost estimates do not include the costs for in-house human resources as they can vary significantly across different hospitals.

Assumptions
1. It is assumed that the costs of maintaining smart infusion pumps are not significantly different from maintaining traditional pumps. Also, the estimate is based on an in-house supported technology.
2. The CQI data analysis consulting fee is for vendor consultations outside the basic training provided as a part of implementation.
3. The wireless infrastructure establishment estimate is based on the following assumptions:
   - It is not clinically important that a pump fails to receive a drug library update at a very specific time. It is acceptable that it receives the update several hours after a new drug library file is uploaded to the central server.
   - The hospital building is square/rectangular. Each floor is approximately 8000 sq ft.
   - Consistent densities of typical construction materials (concrete, drywall), interference, people (all impact RF signal)
• Power over Ethernet (PoE) switches to connect and power Access Points (APs) are staggered to serve multiple floors.
• Net new install (no existing wireless infrastructure to leverage; e.g. controllers, management consoles)
• Solution cost includes wireless controllers, security mechanisms and centralize management services.
• AP densities are to Location Based Services (LBS) densities – allows for asset tracking
• The cost only captures the capital costs required to procure hardware (no implementation or operational costs).
• The cost does not include discounting or preferred vendor pricing.

Key Findings:
• IV administration errors present a serious problem for hospitals.
• Traditional, general-purpose infusions devices do not address the problem as they cannot limit doses or be readily customized for patient or treatment specific populations.
• Although smart infusion systems have been developed to enhance patient safety, results of studies that have compared the benefits of traditional versus smart pump systems have been mixed.
• Optimized use of smart pumps is dependent on proper implementation.
• Implementation process for smart pump technology is more complex, and requires a larger coordinated effort with stakeholders involved throughout the medication process, compared to implementation of traditional pumps.
• Implementation of smart pumps is much more costly than implementation of traditional pumps.
• Smart pumps should be integrated with other information systems.
• Integrated system revolves around standardized drug concentrations and dosing units, bar coding, wireless networking, Positive Patient Identification (PPID), Computerized Physician Order Entry (CPOE), and electronic medical administration records (eMARs).
• 13% of Ontario hospitals currently use smart pumps and another 6% are in the process of implementing smart pumps.
• There are currently eight licensed smart pump products in Canada from five different vendors (i.e., Baxter, BBraun, Cardinal, Hospira, and Sigma).
• Three manufacturers (Baxter, Cardinal, and Hospira) dominate the Ontario health care market for smart pump systems.
• Most current Ontario smart pump adopters are located around the Greater Toronto Area (GTA).
• Upfront and ongoing costs associated with adoption of smart IV infusion pumps are much higher than those linked to traditional pumps.
3 Lab Study Results

To our knowledge, there has been no study that has empirically tested the effects of pump technology on safe medication administration by conducting a controlled experiment in which different types of pump technology are manipulated. We therefore conducted an experimental study in which we directly manipulated the type of pump (i.e., traditional vs. smart vs. smart with bar coding) and type of infusion tasks (with some planted errors) to investigate the impact of different types of infusion pumps on nurses ability to safely deliver IV medications. Furthermore, the results of this research are expected to highlight key issues associated with infusion systems and inform development of potential interventions to mitigate the effects of these issues.

3.1 Method

3.1.1 Participants

Twenty-four nurses (4 males and 20 females) from seven clinical areas (i.e., cardiac intensive care unit, cardiovascular intensive care unit, emergency, general surgery, general internal medicine, post anesthesia care unit, transplant) participated in this experiment. Each nurse was remunerated for their participation. University Health Network Research Ethics Board (REB) approval was obtained.

The participants were in the following age ranges: fifteen were between the ages of 18 and 35, two were between the ages of 36 and 45, and seven were between the ages of 46 and 60.

3.1.2 Design

The participants delivered IV infusions in each of three pump type conditions (i.e., traditional, smart, bar code) under 7 different task conditions (i.e., wrong drug, wrong patient, wrong dose-hard limit, wrong dose-soft limit, drug not in library, secondary infusion-maintenance fluid, and secondary infusion-therapeutic drug). Thus, the design was a 3 (pump type) x 7 (infusion task) repeated measures design. Four of the task conditions (i.e., wrong drug, wrong dose-soft limit, drug not in library, and secondary infusion-therapeutic drug) required intermittent infusions and the other three tasks (i.e., wrong patient, wrong dose-hard limit, and secondary infusion-maintenance fluid) required continuous infusions. Figure 3 provides an outline of the experimental design. The order of the task conditions and pump types were counterbalanced to avoid carry-over effects.
The extent to which the information provided on the physician order matched the entries required by the pumps varied as a function of the type of infusion (i.e., continuous vs. intermittent; see Figure 4). Specifically, a physician order for continuous infusions displayed the dose, rate and volume to be infused which was consistent with the entries required by all three pumps. For intermittent infusions, the information provided on a physician order (i.e., dose, duration, volume) matched the entries required by the smart pump and the bar code pump (i.e., duration and volume), but did not match the entries required by the traditional pump (i.e., rate, volume). Therefore, participants were required to perform a conversion calculation when entering intermittent infusion parameters in the traditional pump.

<table>
<thead>
<tr>
<th>Infusion Type</th>
<th>Information Provided on Physician Order</th>
<th>Entries Required by Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>Dose, Rate, Volume</td>
<td>Rate, Volume, Dose, Rate, Volume</td>
</tr>
<tr>
<td>Intermittent</td>
<td>Dose, Duration, Volume</td>
<td>Rate, Volume, Duration, Volume</td>
</tr>
</tbody>
</table>

= Match between physician order and entries required by nurse

= Mis-match between physician order and entries required by nurse

Figure 4: Match between physician order and pump menus

3.1.3 Location and apparatus

3.1.3.1 Lab

The experiment was conducted in labs that allow high fidelity re-creations of clinical environments. Specifically, we simulated an inpatient unit environment, including patient beds, furniture, computerized physician order entry system, IV infusion equipment (e.g., IV bags, tubing sets, labels, etc), and paperwork. These labs were
equipped with multiple ceiling-mounted cameras and microphones, had observational booths with one-way glass, and had full video and audio recording and editing facilities. No actual drugs or patients were used. Rather, water was used in place of drugs and mannequins were used in place of patients. Physician orders were presented on a CPOE system to reflect how nurses in this study currently view physician orders.

3.1.3.2 Pumps

Three pumps (i.e., traditional, smart, bar code) were selected from 2 different manufacturers. Specifically, the traditional pump was from one manufacturer and the smart pump and bar code pump were both from another. That is, the bar code pump was the same vendor product as the smart pump, but with bar coding enabled.

Regarding the bar code pump, we replicated an environment where the pump scanner could be used to (1) scan the bar code on the patient armband, (2) scan the nurse badge, and (3) scan the bar code on the medication IV label. Therefore, the bar code pump could detect if the patient information on the drug label matched the patient information on the armband; thereby ensuring the infusion was being administered to the right patient. In a fully integrated system, the bar code pump server would communicate with the Computerized Physician Order Entry system (CPOE) and/or the Pharmacy Information System (PhIS) and consequently, would ensure compliance with other rights (i.e., right drug, right dose, right route, and right time). However, given that smart pump manufacturers and hospital IT vendors have not yet fully established an integrated approach that ensures connectivity between all medication management technologies; we opted to implement the bar code pump in the form that most hospitals can currently accommodate.

3.1.3.3 Tasks

Participants were required to perform IV infusions under various task conditions. Tasks and associated medication orders and drug labels were designed with the help of pharmacists and nurses to ensure validity. Table 6 describes the six different tasks.

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong Drug</td>
<td>The nurse was provided with an IV bag containing a drug that did not match the drug prescribed on the physician order. The two drug names, however, were selected such that they were look-alike-sound-alike drugs. If and when the nurse participant detected the mismatch between the drug label and the physician order, the confederate nurse (i.e., actor playing the role of a nurse) provided the nurse participant with the proper IV medication bag (i.e., IV bag with drug label matching physician order).</td>
</tr>
</tbody>
</table>
Wrong Patient

The mannequin in the patient bed was not the patient for whom the physician’s order was prescribed. That is, the patient identification armband on the mannequin did not correspond to the patient information (name and medication registration number) on the physician order. If and when the nurse participant detected the mismatch, the confederate nurse contacted the orderly (i.e., an actor playing the role of the orderly) who then replaced the incorrect patient mannequin with the correct patient mannequin.

Wrong Dose-hard Limit

Dose provided on the physician order was outside of the allowable hard limit specified in the hospital’s IV formulary; thus the dose was clinically inappropriate.

Wrong Dose-soft Limit

The dose provided on the physician order was outside of the allowable soft limit specified in the hospital’s IV formulary; thus the dose was clinically inappropriate.

Drug not in Library

The drug prescribed on the physician’s order was not contained in the smart pump and bar code pump drug library. Given that the traditional pump did not contain a drug library, this manipulation was not expected to affect task performance when interacting with this pump. When interacting with the smart and bar code pumps, however, the nurse participant had to first look for the drug in the library, detect that it was not there and program via a basic infusion where no safeguards were present.

Secondary Infusion task (maintenance fluid and therapeutic drug)

Nurse participant was required to program both a maintenance infusion and a secondary (also referred to as “piggyback”) infusion. Although no errors were planted in this condition, we assessed the prevalence and nature of errors associated with secondary intravenous infusions.

Table 6: Task description
3.1.4 Procedure

Each participant was provided with a 15 minute training session on a given pump. Specifically, the training covered the main programming tasks required in the experiment and was based on typical vendor instruction. Participants were then asked to complete various infusion tasks in the simulated clinical environment. When the experimental condition began, there were three patient mannequins in separate beds in the unit. Participants were briefed by a confederate nurse on the patients’ medical histories, given physician orders for IV infusions, and asked to program the pumps accordingly. The confederate nurse remained present in the room to ensure participants conducted the tasks in the required sequence. If participants became stuck or confused they were asked to communicate with the confederate nurse. Participants then received training on another pump and the procedure repeated itself until all three pumps had been evaluated.

Behind a one-way mirror, the test facilitators recorded the number of errors remedied, accuracy of the entries on the pump, and any other observations made.

3.2 Results

Each participant completed a total of 21 infusions. Cochran’s Q test (a measure for correlated dichotomous outcomes) was used to assess (a) error resolution, (b) pump programming accuracy, and (c) success rate of secondary infusions, all as a function of pump type (i.e., traditional vs. smart vs. barcode). The Cochran Q tests were followed by pairwise comparisons between the different combinations of pump types by use of the McNemar $\chi^2$ test. Pairwise comparisons were made using Bonferroni correction.

3.2.1 Error resolution

Error resolution was assessed for the four conditions in which errors were planted (i.e., wrong drug, wrong patient, wrong dose-hard limit, and wrong dose-soft limit).

3.2.1.1 Wrong drug

Out of the 72 infusions which contained planted drug errors (i.e., three drug errors per participant), participants remedied the error on 43 (59.7%) of these entries. Type of pump did not significantly impact nurses’ ability to remedy the wrong drug error ($p > 0.1$). Thus, none of these pumps helped nurses remedy wrong drug errors.

3.2.1.2 Wrong patient

As shown in Figure 5, there was a significant difference in nurses’ resolution of patient ID errors across the three different types of pumps [Cochran Q = 14.36; df = 2; $p < 0.05$]. Specifically, the number of nurses (out of a total of 24) who remedied patient identification errors was significantly higher when using the barcode pump 21 (88%) than when using either the traditional pump 11 (46%) or the smart pump 14 (58%). The difference between the traditional pump and the smart pump, however, was not significant. Thus, the automatic patient identification verification on the barcode pump appears to have significantly increased nurses’ resolution of wrong patient errors.
3.2.1.3 Wrong dose hard limit

As shown in Figure 6, there was a significant difference in the number of wrong dose-hard limit errors remedied by nurses across the three different types of pumps [Cochran Q = 12.13; df = 2; p < 0.003]. Specifically, the number of nurses who remedied critical overdose errors was significantly higher when using the smart pump 18 (75%) and the barcode pump 19 (79%) than when using the traditional pump 9 (38%). Thus, the results suggest that when nurses are faced with hard (unchangeable) limit alerts, they typically correctly remedy the error. Participants’ who failed to correctly remedy the error when using the smart pump and the barcode pump, opted out of the dose-checking technology after hitting the hard limit and used the pump in its standard rate-based mode (i.e., no-safeguard mode).
3.2.1.4 Wrong dose soft limit

There was no significant difference in nurses’ ability to remedy soft limit overdose errors across the three types of pumps [error remedied by 12 (50%) participants when using the traditional pump vs. 15 (62.5%) participants when using the smart pump vs. 18 (75%) participants when using the barcode pump; \( p > 0.1 \)]. Therefore, despite the fact that the smart pump and the barcode pump provide out-of-limit alerts, many nurses elected to override the alert and continue infusing the medication. Thus, the results indicate that when nurses are provided with the flexibility to override a limit, they often do so, even when clinically inappropriate.

3.2.1.5 Pump programming accuracy

Pump programming accuracy when using the three types of pumps was assessed for (1) continuous infusions and (2) intermittent infusions.

1. Continuous Infusions (no conversion required across all pumps):

For continuous infusions, no conversion calculations were required because the information provided on the physician order was consistent with the information needed by the nurse to program the three types of pumps. Continuous infusions were assessed in the following 3 tasks: (1) wrong patient, (2) wrong dose-hard limit, and (3) maintenance fluid. Within each task, a Cochran Q test was performed on the number of accurate entries as a function of pump type.

As shown in Figure 7, for all three tasks requiring continuous infusions, there was no difference in the number of accurate entries across the three pump types \( (p > 0.1 \) for all three tasks). Altogether, 216 continuous infusions were performed, and participants were accurate on 203 (93.98%) of these entries. Thus, it appears that when the parameters included on the physician orders match the parameters required from the pump, participants’ entries were overall very accurate, regardless of the type of pump.

![Figure 7: Percentage correct entries for continuous infusions as a function of pump type](image)
2. Intermittent Infusions (conversion required for the traditional pump vs. no conversion required for the smart pump and barcode pump):

For intermittent infusions, although no conversion calculations were required when using the smart pump and the barcode pump, conversions were required when programming the traditional pump because the information provided on the physician order was not in accord with the parameters required by the pump. Intermittent infusions were assessed in the following 3 tasks: (1) wrong drug, (2) wrong dose-soft limit, and (3) secondary infusion-therapeutic drug. Within each task, a Cochran Q test was performed on the number of accurate entries as a function of pump type.

As shown in Figure 8, for all three tasks requiring intermittent infusions, participants’ entries were significantly more accurate when using the smart pump and the barcode pump than when using the traditional pump (wrong drug: \( p < 0.001 \); wrong dose-soft limit: \( p < 0.01 \); secondary infusion-therapeutic drug: \( p < 0.003 \)). Altogether, 72 intermittent infusions were performed in each of the pump type conditions (i.e., traditional, smart, barcode). Participants were accurate on 42 (58%) infusions performed using the traditional pump, 67 (93%) infusions performed using the smart pump, and 65 (90%) infusions performed using the barcode pump. The magnitude of entry errors varied between 1.2 to 6 times higher than the correct parameter. Thus, the mismatch between physician order and the traditional pump menu forced users to perform a conversion, and consequently affected participants’ ability to enter accurate settings.

Figure 8: Percentage correct entries for intermittent infusions as a function of pump type

3.2.1.6 Secondary infusion errors

There was no significant difference in nurses’ ability to successfully program secondary infusions across the three types of pumps (\( p > 0.1 \)). Altogether, 24 secondary infusions were performed in each pump type condition. Participants successfully programmed 12 (50%) secondary infusions when using the traditional pump, 16 (67%) when using the smart pump, and 12 (50%) when using the barcode pump. The frequency, percentage, and potential consequences of these errors are shown in Table 7. Thus,
incidences of severe errors when administering secondary infusions were high across all three types of pumps.

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Frequency (n=32)</th>
<th>Percentage</th>
<th>Potential Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bag Mis-Alignment (e.g., positioning the therapeutic drug bag at or below the level of the maintenance fluid bag)</td>
<td>12</td>
<td>37%</td>
<td>Mixing and concurrently delivering the therapeutic and maintenance fluids, possibly at incorrect rates.</td>
</tr>
<tr>
<td>Programming Errors (e.g., conversion calculation errors)</td>
<td>9</td>
<td>28%</td>
<td>Delivering the maintenance fluid and/or the therapeutic drug at an incorrect rate.</td>
</tr>
<tr>
<td>Confusion in the Programming Sequence (e.g., programming the therapeutic drug at the rate of the maintenance fluid)</td>
<td>6</td>
<td>19%</td>
<td>Therapeutic drug being infused at the rate of the maintenance fluid.</td>
</tr>
<tr>
<td>Forgetting to Open the Clamp on the Therapeutic Tubing</td>
<td>3</td>
<td>9%</td>
<td>Accidental administration of the maintenance fluid when intending to initiate the therapeutic drug infusion, and the maintenance fluid being infused at rate of therapeutic drug.</td>
</tr>
<tr>
<td>Tubing Arrangement Errors (e.g., connecting the infusion line from the therapeutic drug bag into the wrong port on the primary infusion line)</td>
<td>2</td>
<td>6%</td>
<td>Free-flowing therapeutic drug into the patient.</td>
</tr>
</tbody>
</table>

Table 7: Frequency, percentage, and potential consequences of secondary infusion errors

### 3.3 Discussion

Overall, we found that nurses’ ability to safely administer medications was enhanced when using the smart pump and bar code pump compared to when using the traditional pump. However, serious errors still occurred. Errors that were potentially
preventable by a smart pump or a bar code pump (e.g., soft limit overdose errors) were due to deviations from policies (e.g., overriding a soft limit when clinically inappropriate). Some errors, such as those made while performing secondary infusions, were not preventable by smart or bar code technologies. Other errors (e.g., undetected wrong drug errors) were due to a lack of interface between the pump and other components (e.g., CPOE) of the medication delivery system. Thus, effective use of pump technology is dependent not only on the design of the pump itself but also on the way it is implemented into the institution. The present study adds to the literature by explicitly comparing and quantifying the effects of different types of pump technology on nurses’ ability to safely administer IV medication, and by identifying errors that are not addressed by any of the current IV pump technologies.

3.3.1 State of smart pumps

Many hospitals are turning to smart infusion pumps. Results of the 2007 American Society of Health-System Pharmacists (ASHP) national survey on informatics found that an estimated 44.0% of US hospitals use smart pumps. Smart infusion pumps have been proposed as a technique to increase the safety of intravenous medication administration practice by reducing drug errors at the point of delivery. While smart pumps help reduce certain errors related to IV administration, they do not address many of the major concerns. For example, although smart pumps detect and alert users as to soft and hard limit overdose errors, users often do not respond to these alerts in a safe manner. Specifically, the results of the present study are consistent with results from other researchers who have shown that nurses often override soft limit alerts. The results of the present study, however, suggest that when nurses are faced with hard limit warnings, which do not allow them to override but rather force the re-programming of the pump setting, nurses do indeed respond in a safe manner. In practice, many hospitals do not activate hard limits when implementing smart pumps. Furthermore, smart pumps may cause nurses to make new types of errors (e.g., selecting the incorrect drug concentration). For example, researchers have suggested that overdoses have occurred due to confusion between dosing units and/or concentrations. The results of the present research support this view and provide further evidence that unnecessary variation in IV medication practices (e.g., mismatch between parameters presented on physician order and parameters required on pump menu) is associated with increased risks. Smart pumps, in their current form, are limited in that they help prevent errors resulting from incorrect programming that exceed preset dose limits, but do not ensure that the right drug is delivered to the right patient, or that the programmed dose matches the physician’s order. Thus, institutions must promote a culture of safety which encourages nurses to think critically, evaluate pump warnings, and limit overrides to circumstances that have been duly assessed, while moving toward a complete integration of systems to ensure safe medication delivery.

To ensure optimized integration of smart pumps, healthcare institutions must dedicate a significant operational budget to cover costs including the following: maintenance and licensing, drug library updating, continuous quality improvement analysis and reporting. Although smart pumps can decrease the likelihood of errors resulting from incorrect programming, they will fail to improve medication safety unless
technological and behavioural factors are addressed. Currently, hospitals may be investing three to four times more money into smart infusion pumps compared to traditional pumps without realizing any significant safety benefit. It is imperative that healthcare institutions understand the limitations of the pump technology while recognizing ways to maximize their potential benefits.

3.3.2 State of smart pumps with bar coding

While bar coded infusion pumps hold significant promise, the current reality is that manufacturers and hospitals are not yet ready to provide an optimal fully integrated system. That is, smart pump manufacturers and hospital IT vendors have not yet fully established an integrated approach that ensures connectivity between all medication management technologies (e.g., bar code pumps, CPOE, PhIS). This is in part due to the fact that many hospitals do not have the proper infrastructure in place to support this comprehensive approach to patient safety. The results of the present study show that until hospitals are ready to accommodate full connectivity between all medication management technologies, bar code technology will help prevent certain errors that earlier pump versions could not address, such as wrong patient errors, but will be susceptible to many of the same errors (e.g., wrong drug) as other types of pumps. Thus, despite best efforts, implementation of stand-alone systems that lack a holistic approach to addressing medication administration issues may lead to fragmented solutions that do not address the problem as intended.

3.3.3 Conversion errors

Many risks surrounding IV infusion practice are a result of the unnecessary complexity and variability in drug prescribing and administration practices. The results of the present study show that complex calculations required by nurses to administer medications lead to errors. These complex calculations are often required because the information provided on the physician order and/or on the pharmacy generated drug label are not in accord with the information needed by the nurse to program the pump. That is, information required to program the pump (e.g., rate in ml/hr) often does not match the information provided on the physician order (e.g., mg/min) and consequently nurses are required to perform complicated mathematical calculations to convert the dose (e.g., in mg/min) to a rate (e.g., in ml/hour). Thus, the present findings provide an important perspective on the need for a systems approach which focuses on (a) understanding the complex drug administration process and (b) designing safeguards to help reduce the opportunities for error.

3.3.4 State of secondary infusions

A high incidence of errors in the administration of secondary intravenous infusions was found across all three types of pumps (i.e., traditional, smart and bar code). Many of these errors (e.g., bag mis-alignment, tubing arrangement, forgetting to open the secondary clamp) have the potential to cause serious harm to patients and are not mitigated by any pump infusion technology. These results are consistent with findings from other researchers who indicated that a high frequency of use errors related to the setup and administration of secondary infusions have lead to adverse events. Errors
related to pump setup are not limited to secondary infusions. That is, nurses sometimes mix-up the infusion lines or pump channels when setting up or programming IV pumps, and these errors are not mitigated by current technology\(^{35}\). For example, bar coding can ensure that the proper solution is hung but cannot detect if the tubing is inadvertently switched with another solution during pump set-up. Thus, risks associated with secondary and/or multi-channel infusions represent a serious patient safety issue and must be addressed.

### 3.3.5 Limitations/future work

The results of the present study provide information concerning the potential for pump technology to enhance the IV medication administration practice, when the infusion tasks have demands comparable to those in the experiment. Performance of other infusion tasks, such as infusing a bolus, is also expected to vary as a function of the type of pump technology used, and therefore should be subject to future study. Our results also provide evidence that we must consider how different components of the medication delivery process interconnect (e.g., information on physician order should match entries required by pump).

<table>
<thead>
<tr>
<th>Key Findings:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Effective use of pump technology is dependent not only on the design of the pump itself but also on the way it is implemented at the institution.</td>
</tr>
<tr>
<td>• Soft limits (that can be overridden) in smart infusion pumps had no significant effect in preventing dosing errors.</td>
</tr>
<tr>
<td>• Hard (unchangeable) limits prevented dosing errors, thereby increasing patient safety.</td>
</tr>
<tr>
<td>• Many risks surrounding IV infusion practice are a result of the unnecessary complexity and variability in drug prescribing and administration practices.</td>
</tr>
<tr>
<td>• Until barcode pumps are integrated with other systems within the medication administration process, their role in enhancing patient safety will be limited as they are susceptible to many of the same errors (e.g., wrong drug) as other types of pumps.</td>
</tr>
<tr>
<td>• Further improvements to pump technologies are needed to mitigate risks associated with IV infusions, particularly secondary infusions.</td>
</tr>
</tbody>
</table>
4 Field Study Results: Current State of Smart Pump Adoption in Ontario

To provide clearer estimates of the adoption of smart pump systems by Ontario hospitals, the University Health Network’s (UHN) Healthcare Human Factors Group (HHFG) measured the adoption rate of smart pump systems and identified emerging key factors to successful migration from traditional to smart infusion pump systems. The goal was to gather accurate information on current levels of adoption and to provide feedback that could be used to help guide other hospitals in their future migration endeavors.

4.1 Method

4.1.1 Participants

Nineteen Ontario hospitals geographically dispersed around the province took part in this study. Of these 19 hospitals, 13 were hospitals who were already using smart large volumetric infusion pumps, and 6 were hospitals who were in the process of migrating from traditional large volumetric infusion pumps to smart large volumetric infusion pumps. Research Ethics Board (REB) approval was obtained.

4.1.2 Questionnaires

Two separate questionnaires were designed. Many questions were contained in both questionnaires. Some questions, however, were specifically designed for hospitals that had already completed the migration from traditional to smart large volumetric infusion pumps while other questions were designed for hospitals that were in the migration process. Questionnaires covered the following four main themes: (1) motivation for migration, (2) stakeholder engagement, (3) acquisition process, (4) data analysis and reporting.

4.1.3 Procedure

In late 2008 and early 2009, the Healthcare Human Factors Group (HHFG) conducted phone interviews and distributed questionnaires to Ontario hospitals who had either already migrated to a smart infusion system or who were in the process of migrating.

4.1.4 Data analysis

Descriptive statistics are reported and Cochran’s Q test (a measure for correlated dichotomous outcomes) was used to assess how hospitals’ ratings differed on certain questions. The Cochran Q tests were followed by pairwise comparisons between the different combinations of pump types by use of the McNemar $\chi^2$ test. Pairwise comparisons were made using Bonferroni correction.
4.2 \textbf{Results}

This section contains the main results from the field study. Further results are presented in the Appendix.

4.2.1 \textbf{Demographics of smart pump adopters that participated in the study}

4.2.1.1 \textbf{Ontario adoption rate for hospitals that participated in the study}

Overall, 70\% of Ontario hospitals that currently use smart pumps, and 56\% of Ontario hospitals that are in the process of migrating from traditional pumps to smart pump systems, participated in the study (see Table 8).

<table>
<thead>
<tr>
<th>Status</th>
<th>Number of Hospital Interviewed</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently Implemented</td>
<td>13</td>
<td>65.0%</td>
</tr>
<tr>
<td>In process</td>
<td>6</td>
<td>66.7%</td>
</tr>
</tbody>
</table>

Table 8: Smart pump adoption in Ontario hospitals that participated in the study

4.2.1.2 \textbf{Market penetration of smart pump systems in Ontario hospitals that participated in study}

Figure 9 displays the market penetration of smart pumps in Ontario hospitals that participated in the study. The distribution correlates with the market penetration of smart pumps in Ontario.

Figure 9: Market penetration of smart pumps in Ontario hospitals that participated in study (includes current users and in process)
4.2.2 Wireless infrastructure

Out of the 19 hospitals that participated in the study, 9 hospitals (47%) had wireless infrastructure capability. However, only 6 hospitals (32%) used their smart pumps wirelessly, as the remaining 3 hospitals purchased pumps that did not have wireless capability. Thus, a total of 13 hospitals (68%) did not use their pumps wirelessly (see Figure 10).

![Figure 10: Percentage of current smart pump users that use their smart pumps wirelessly vs. those that do not](image)

4.2.3 Standardized concentrations

As shown in Figure 11, out of the 13 hospitals that currently use smart pumps, 3 hospitals (23%) only have standardized concentrations for some of their drugs and 10 hospitals (77%) have standardized concentrations for most of their drugs.

![Figure 11: Percentage of current smart pump users that have standardized concentrations for most or for a partial set of their IV drugs](image)

4.2.4 Physician order entry

Out of the 19 hospitals that participated in the study, 3 hospitals (16%) had computerized physician order entry systems. Eight hospitals (42%) used paper-based standard orders, 5 hospitals (26%) used paper-based free-text orders and 3 hospitals (16%) used a mix of paper-based standard orders and free-text orders (see Figure 12).
4.2.5 Motivation for migrating to smart pumps

There was a significant difference in hospitals’ reasons for migrating to smart pumps [Cochran Q = 24.94; df = 4; p<0.001] (see Figure 13). Specifically, out of the total 28 ratings, hospitals rated “inventory age and failure” (15 ratings, 53.6%) as the reason for migrating to smart pumps significantly more often than the remaining categories (critical incident: 14.3%; literature: 7.1%; push from manufacturer: 7.1%; safety strategy: 17.9%). There were no significant differences between any other categories.

Figure 13: Frequency of responses by Ontario hospitals for motivation to migrate from traditional IV infusion pumps to smart IV infusion systems
4.2.6 Stakeholder engagement

There was a significant difference in the type of stakeholders that hospitals’ involved throughout the migration process \((\text{Cochran } Q = 35.59; \text{ df } = 5; p<0.001)\). Figure 14 displays the frequency and percentage of each stakeholder’s involvement. Out of 19 hospitals who answered this question, hospitals engaged nursing (19 hospitals, 100%) and pharmacy (17 hospitals, 89%) significantly more often than risk management (7 hospitals, 37%), IT (5 hospitals, 26%), and physicians (8 hospitals, 42%). Although hospitals engaged nursing and pharmacy more often than biomedical engineering (12 hospitals, 63%), the difference was not significant. In sum, many institutions neglected to form a multidisciplinary team, and consequently, many key stakeholders (e.g., pharmacy, IT, risk management) were not involved in the process.

![Figure 14: Frequency of stakeholder engagement throughout the migration process from traditional pumps to smart pump systems (n=19)](image)

4.2.7 Acquisition process

There was a significant difference in the system components that the hospitals evaluated prior to their smart pump selection \((\text{Cochran } Q = 22.30; \text{ df } = 3; p<0.001; \text{ see Figure 15})\). Out of the 13 hospitals who answered the question as to whether or not they conducted a hands-on evaluation of different systems components, the number of hospitals who reported evaluating the actual smart pump (11 hospitals, 79%) was significantly higher than the number of hospitals who reported having evaluated the drug library software (2 hospital, 14%) and the reporting software (0 hospitals, 0%). Although hospitals evaluated the pump more often than the wireless abilities (4 hospitals, 29%), the difference was not significant. Thus, many hospitals focused solely on the pump itself and neglected to evaluate all system components.
Figure 15: Frequency of hands-on evaluation of smart pump system components

### 4.2.8 Data analysis and reporting of smart pump log

#### 4.2.8.1 Drug library compliance

Compliance with drug library was defined as use of the drug library settings when programming an infusion rather than programming in the basic (i.e., no safeguard) mode. Out of the 13 hospitals who currently use smart pumps, 7 hospitals (54%) reported that nurses in their institution were not using the drug library at all or only minimally (see Figure 16).

![Pie chart showing drug library compliance](image)

Figure 16: Percentage of drug library compliance for Ontario hospitals currently using smart pumps

#### 4.2.8.2 Overrides

Out of the 6 hospitals for which nurses use the drug library, 4 hospitals (67%) reported having a high rate of soft limit overrides (see Figure 17). High percentage of overrides was defined as more than fifty percent of soft limit warnings being overridden.
Figure 17: Percentage of Ontario smart pump users who experience high/low percentages of soft limit overrides.

4.2.8.3 Implementation of hard limits

Out of the 13 respondents, 8 hospitals (62%) either did not implement or only implemented a few hard limit warnings (see Figure 18).

Figure 18: Percentage of Ontario smart pump users that implemented or failed to implement hard limits.

4.3 Discussion

The results of this field study provide evidence that Ontario hospitals are not following best practice processes regarding planning, use, and support of their smart pump systems when migrating from traditional IV infusion pumps to smart infusion systems. Since infusion pump manufacturers have all but abandoned the development of
traditional pumps in favour of some form of smart pump technology, most hospitals have converted to smart pumps primarily to replace their aging population of traditional pumps and were not necessarily driven by the purported safety rationale of the technology. Consequently, many institutions treated the implementation as they would a traditional infusion pump deployment. For smart pumps’ benefit to be fully realized, a comprehensive drug library must be developed, deployed, maintained, and updated preferably via wireless communication. This requires a human resource and technical infrastructure that many hospitals often are not prepared for. Thus, many institutions have incomplete drug libraries which force clinicians to bypass the pumps’ safeguards thereby circumventing the benefits of the system by reverting to purely manual programming which is prone to error. The following sections provides a summary of the issues stemming from existing practices regarding the planning, configuration, use, and support of smart pump systems.

4.3.1 Wireless infrastructure and standardized concentrations

Although a wireless networked environment is not a crucial requirement to ensuring readiness for smart pump implementation, it is critical to maintaining a practical dose error reduction system. The majority of Ontario hospitals (68%) did not ensure wireless connectivity prior to implementing smart pumps. Furthermore, our findings indicate that although 9 of 19 hospitals (47%) had the wireless infrastructure to support wireless connectivity, 3 hospitals (16%) did not purchase pumps with secure wireless capability. These results suggest that many Ontario institutions are treating deployment of smart pumps as they would a traditional infusion pump, and therefore, are not setting themselves up to reap the benefits smart pumps can offer.

Similarly, some Ontario hospitals (23%) are proceeding with their smart pump implementation without establishing a complete list of standardized concentrations. Standardization of drug concentrations is critical to ensuring synchronicity between physician orders and smart pumps. Without this synchronicity, nurses will be forced to opt out of the safety features of the smart pumps. Thus, it appears that certain institutions have been too quick to adopt smart pump technology without first ensuring their readiness.

4.3.2 Physician order entry

Over 80% of current smart pump users that we interviewed still use paper-based order form, free-text, or a combination of the two. This result highlights the need for a formalized process to be in place to ensure that changes that are made to standardized concentrations in the drug library are also reflected on the pre-printed forms. If not, nurses will receive orders from physicians that are not reflected in the drug library and will therefore bypass the safety features of the pump, and program in manual mode.

4.3.3 Motivation for migrating to smart pumps

Despite the fact that the main purpose of smart pumps is to improve the safety of IV infusions, our findings indicate that most hospitals have converted to smart pumps primarily to replace their aging population of traditional pumps. Hospitals wanting to
replenish their pump inventory were forced to migrate to smart pumps because infusion pump manufacturers stopped the development of traditional pumps. This asynchrony between hospitals’ main motivation and the pumps’ main purpose significantly impacted how hospitals approached the migration process. Specifically, when acquiring and implementing smart pumps, many hospitals treated the process as a simple pump replacement initiative. Consequently, they did not follow a formal process involving all stakeholders and thus, the safety benefits of smart pumps were not realized.

4.3.4 Stakeholder engagement

Our findings indicate that many institutions neglected to form a multidisciplinary team, and consequently, many key stakeholders (e.g., pharmacy, IT, risk management) were not involved in the process. As a result, these institutions lacked the resources and skills required to develop and maintain different components of the system. For example, one site did not involve pharmacy despite the fact that pharmacy plays an essential role in developing and maintaining the drug library. Some sites involved pharmacy in the initial development of the drug library but did not plan nor budget for their involvement in the ongoing maintenance of the library. Consequently, many institutions have incomplete drug libraries which force clinicians to bypass the drug library, thereby circumventing the safety features of the pump.

4.3.5 Data analysis and reporting of smart pump logs

We found that over 30% of Ontario smart pump users have never once looked at the pump log data. Our findings are consistent with US reports that more than half of hospitals with smart infusion pumps do not use logs for quality improvement purposes. Furthermore, similarly to US hospitals which only have 29.9% smart pump users with wireless capability, our findings showed that only 32% of Ontario hospitals have smart pumps with wireless capability. Therefore, analysis of CQI data for the remaining 68% of hospitals entails physically locating each pump, and manually uploading and downloading data which is extremely labor intensive. Still, institutions that had wireless features implemented stated that the reporting capability was very immature and quality reports were not readily generated. Thus, the majority of institutions are uninformed as to (1) how well smart pump features are being used, and (2) whether smart pump technology actually increases the safety of their intravenous medication administration practice.

4.3.5.1 Drug library compliance

Our findings show that 54% of Ontario smart pump users are not using the drug library at all or only minimally. Our findings are consistent with results from other studies that have found that clinicians bypass smart pumps’ dose-checking technology, thereby circumventing the safety features of the pump. Hospitals attributed the following as reasons for not using the technology: extra steps to use the technology, perception that technology is not useful because drug library is not complete and/or updated regularly, resistance to change. Institutions must recognize that implementation of new smart pump technology does not solely involve initial drug library development and pump distribution. Rather, successful smart pump implementation is dependent on
continuously educating clinicians on the safety benefits of the technology, and promoting a culture of safety that urges clinicians to use the safety features and/or voice their concerns when the technology does not meet their needs.

4.3.5.2 Overrides

Although smart pumps detect and alert users as to soft limit (i.e., can be overridden) and hard limit (i.e., cannot be overridden) overdose errors, users often do not respond to these alerts in a safe manner. Our findings show that 67% of Ontario smart pump users reported having a high rate of soft limit overrides. That is, most institutions reported that nurses often ignore and override soft limit alerts. This result is consistent with results from other researchers\textsuperscript{40,9,41} who have shown that clinicians often override soft limit alerts. Thus, while soft limits can be beneficial in that they allow clinicians to make the ultimate decision about infusion parameters, they can negate the benefits of having a drug library if clinicians simply ignore the alerts. Studies have shown that clinicians bypass the safety features of other technologies as well. For example, it has been reported that drug safety alerts on Computerized Physician Order Entry (CPOE) systems are overridden by clinicians in 49% to 96% of instances\textsuperscript{48}. Efforts must be made to increase the relevance and correct use of drug safety alerts without burdening clinicians.

4.3.5.3 Implementation of hard limits

Our findings reveal that most institutions (i.e., 62%) do not implement hard limits or only implement a few. This result is consistent with other studies which have reported that hospitals do not use or make minimal use of the hard limit feature\textsuperscript{25,7}. Respondents in our study stated that the main reason for not implementing hard limits was that hard limits are too difficult to set because of the wide dosage range required for some drugs. By not implementing hard limits, many smart pump users are evading the software dosing safeguards that make pumps smart, consequently reducing the benefits of having a drug library.

4.4 Conclusion

In sum, the results of our interviews indicate that most Ontario healthcare facilities that are migrating from standard pumps to smart pumps are unaware of the need for a different implementation process, and therefore, are failing to deploy an integrated system. Consequently, these institutions are investing three to four times more money into infusion pumps without realizing any safety benefit.
**Key Findings**

- Adoption rate and optimal use of smart large volumetric infusion pumps in Ontario has been low.
- Most healthcare facilities that are migrating from traditional pumps to smart pumps are unaware of the need for a different implementation process, and therefore, are failing to deploy an integrated system.
- Although smart pumps have the potential to improve medication administration delivery, many financial, technological, and behavioural factors must be addressed to ensure optimal system use.
- 68% of Ontario hospitals did not ensure wireless connectivity prior to implementing smart pumps.
- Although 47% of hospitals had wireless infrastructure, 3 hospitals (16%) did not purchase pumps with secure wireless capability. These results suggest that many Ontario institutions are treating deployment of smart pumps as they would a traditional infusion pump, and therefore, are not setting themselves up to reap the benefits smart pumps can offer.
- 23% of Ontario hospitals that were interviewed are proceeding with their smart pump implementation without establishing a complete list of standardized concentrations. Standardization of drug concentrations is critical to ensuring synchronicity between physician orders and smart pumps.
- 67% of Ontario smart pump users reported having a high rate of soft limit overrides.
- 62% of Ontario smart pump users reported not having implemented hard limits, or only having implemented a few.
- Respondents in our study stated that the main reason for not implementing hard limits was that hard limits are too difficult to set because of the wide dosage range required for some drugs.
- By not implementing hard limits, many smart pump users are evading the software dosing safeguards that make pumps smart, consequently reducing the benefits of having a drug library.
5 Roadmap to Recommended Migration Process

This section presents a roadmap to support successful migration from traditional (non-smart) pump technology to a smart IV infusion system. The roadmap presents a series of steps to help healthcare institutions make implementation choices, and can be used to evaluate potential trade-offs. Figure 19 displays the main phases of the roadmap from the readiness assessment phase through to its ongoing operation and maintenance.

Figure 19: Main phases of the roadmap from the planning phase through to its ongoing operation and maintenance

5.1 Project Planning and Management

5.1.1 Conduct a readiness assessment

The project team must develop a clear understanding of the smart pump system, its purpose, the operational environment in which it is deployed, and the users of the system. The team must also have a keen understanding of the organization’s goals and objectives for implementing the system.

Given that previous generations of IV pumps did not use drug libraries and did not connect to wireless servers, this readiness assessment is new to IV pump implementation. Implementation of smart infusion pump systems requires a formal process which involves many stakeholders throughout the medication process, and should not be viewed as a pump replacement initiative but rather as a patient safety initiative.\textsuperscript{49}

There are certain requirements that should be met to ensure readiness for smart pump implementation. Specifically, a first requirement is to have standardized drug concentrations and dosage units, as it is a crucial step in creating the necessary drug library. Furthermore, an agreed-upon list of standardized IV medication concentrations and dosing units is critical to ensuring synchronicity between physician orders and smart pumps. If the list of drug concentrations available for selection in the smart pump does not contain the drug concentration provided on the physician order, the nurse will be unable to make a selection in the drug library and will be forced to program the pump in the manual mode which has no safeguards.\textsuperscript{49} Thus, standardization of IV medication
concentrations and dosage units is a “must have” criterion because variation in practice can result in dosage errors leading to serious patient injury. (Please refer to section 5.3.1 below for more details on standardization of drug concentrations and dosage units.)

A second requirement that should be considered when assessing readiness for smart pump implementation is the institution’s stage of wireless build. Although presence of a fully built wireless networked environment is not an absolute “must have” requirement, it is highly recommended. Wireless connectivity is a significant enabler of smart pump technology. Specifically, an environment that includes (a) pumps with secure wireless capability, (b) wireless coverage in clinical care areas, and (c) a server to house and process information, enables regular download of data logs and upload of new drug libraries, without the need to physically locate each device. Therefore, a sophisticated wireless infrastructure is critical to maintaining a practical dose error reduction system and enabling software upgrades/ revisions to devices over time. Furthermore, wireless connectivity between smart pumps and other information systems (e.g., CPOE, PhIS, PPID, and eMAR) is ultimately essential to achieve a complete closed-loop medication administration system.

Keeping in mind, however, that hospitals are at various stages of wireless implementation, and that a wireless environment requires a sophisticated network infrastructure that can take time to put in place, use of non-network solutions can be considered in the interim. Specifically, one interim solution is to use a mobile server consisting of a laptop with a wireless router. A mobile server provides most of the benefits of wireless communication (except for real-time information) without requiring a wireless infrastructure. The mobile server is stationed in a given clinical care area while it communicates with pumps in range of the wireless router. Furthermore, the mobile server automatically tracks pumps that it has or has not communicated with, permitting identification of pumps that require follow-up. These mobile servers will need to be widely deployed across the institution, or moved from one location to the next on a regular basis. Alternatively, the only remaining option is to physically locate each pump and manually upload or download information. Thus, regardless of whether institutions have a wireless infrastructure or not, a connectivity strategy for downloading and uploading information should be clearly defined (and budgeted for) during the readiness assessment.

In sum, establishment of standard concentrations and dosing units is a “must have” requirement prior to implementing smart pumps. Furthermore, it is imperative that hospitals ensure synchronicity between standardized concentrations and dosing units contained in smart pump drug libraries and physician order entry systems, regardless of whether physicians’ orders are paper-based or not. A wireless networked environment is strongly recommended when implementing smart pumps but is not an absolute must. However, institutions that plan to physically locate each pump and manually upload and download information should ensure that the proper human resources are allocated for this task. If sufficient time and effort is not invested into the upload and download of information, and its subsequent analysis, the smart pumps will not adequately reflect
nursing practice and nurses will resort to unsafe workarounds and/or they will completely bypass the safety features of the smart pump.

**Key Recommendations:**

- Smart pump system implementation should be viewed and approached as a patient safety initiative rather than a pump replacement initiative.
- Standardized drug concentrations and dosing units are “must have” criterion prior to smart pump implementation.
- Institutions must ensure synchronicity between standard concentration and dosing units contained in smart pumps and in physician order entry system (whether computerized or paper-based).
- Having a wireless network environment prior to smart pump implementation is highly recommended.
- Regardless of institutions’ stage in wireless build, a connectivity strategy for information upload and download must be defined.

### 5.1.2 Understand how smart pumps fit within institutions’ current medication administration process and the added benefit they can provide

The main objective when implementing a smart pump system is to provide safe delivery of IV medications to patients. As with other information technologies designed to help prevent medication errors (e.g., computerized physician order entry, automated dispensing devices), a smart infusion pump system should be integrated within the rest of the medication administration process to ensure its success and optimization. Integration of information technology will help address many of the IV medication errors that are generated during medication ordering, dispensing, administering, and monitoring. However, although an ideal system would consist of a total seamless integration of Computerized Physician Order Entry (CPOE), Pharmacy Information System (PhIS), electronic Medication Administration Record (eMAR), smart IV pumps, Positive Patient Identification (PPID), and Bar-Coded Medication Administration (BCMA), the reality is that most hospitals are not ready for this closed-loop medication administration process. Thus, it is important to recognize that implementation of smart pump technology does not demand the presence of CPOE, PhIS, eMAR, PPID, and BCMA. Smart pump implementation can follow an adaptable approach that allows for incremental benefits while progressing towards a fully integrated process. To assess how smart pumps fit within the ideal closed-loop medication administration process, however, it is important to first understand the workings of a fully closed-loop process. The following is a description of a potential closed-loop medication administration process (see Figure 20 for an illustration):

First, physician’s orders can be transmitted to a smart pump server after being approved by pharmacy. The nurse at the bedside uses a scanner on the smart pump (or a third party scanner) to scan the patient’s armband, the medication label, and his/her nursing badge (in the case where a third party scanner is used, the nurse would also scan
the smart pump). This information is sent wirelessly from the smart pump to the pump server. The pump server, which is electronically linked to the Computerized Physician Order Entry (CPOE), the PhIS, the PPID, and/or the eMAR, tethers the administration to the medication order. If the scanned information matches the physician order, the pump server populates the smart pumps’ parameters according to the stored doctor’s orders. The nurse reviews the entries and starts the infusion. The automated system transmits the infusion with the associated clinician and patient ID to the eMAR.

Figure 20: Example of a potential closed-loop medication administration process
Smart pumps are of great value, even if not wireless or bar code enabled, because they reduce errors related to programming/delivering the wrong dosing unit and/or the wrong drug dose rate. However, integration of smart pumps with other technology systems greatly enhances the effectiveness of the smart pumps\textsuperscript{50,51,52}. For example, seamless integration of smart pumps with CPOE, PhIS, BCMA, PPID, and eMAR help remedy all “5 rights” of medication safety (i.e., right patient, right drug, right dose, right route, and right time). Thus, when planning for the acquisition of smart pumps, institutions should consider what other efforts could be conducted in parallel or sequentially to eventually maximize the potential benefits of smart pump systems.

Recognizing that there is no single correct migration path, as it will vary as a function of the systems institutions already have in place, Figure 21 below presents a summary of the potential benefits achieved through integration of smart pumps with other incremental components of a fully integrated system. While there are a multitude of possible combinations, the following is a description of the six combinations that are highlighted in Figure 21 below:

- **Configuration 1** (displayed in the first column of Figure 21): Institutions that do not have any computerized health information system in place when implementing smart pumps, can improve the safe delivery of IV medications by ensuring that they have standardized concentrations and dosing units. Having a drug library in each pump (which contains standardized concentrations/dosing units) can significantly reduce the programming/delivery of wrong drug dosing rate and wrong drug dosing unit by permitting clinicians to use the Dose Error Reduction System (DERS). However, as mentioned in section 5.1.1 above, it is imperative that hospitals ensure synchronicity between standardized concentrations/dosing units contained in smart pump drug libraries and physician order entry systems, to ensure success.

- **Configuration 2** (displayed in the second column of Figure 21): Institutions that have wireless infrastructure but do not have any computerized health information systems in place when implementing smart pumps, can improve the safe delivery of IV medications by implementing standardized concentrations/dosing units. Furthermore, having wireless infrastructure provides these institutions with the added benefit of being able to regularly update their drug libraries, and analyze their continuous quality improvement data.

- **Configuration 3** (displayed in the third column of Figure 21): Institutions that have standardized concentrations/dosing units, wireless infrastructure, Computerized Physicians Order Entry system (CPOE), and Pharmacy Information System (PhIS) when implementing smart pumps, have the added benefit of real-time synchronization between the systems. For example, if a physician makes a change to an order, the change would automatically be communicated to the pharmacist via the pharmacy information system. After being approved by pharmacy, this information could also be transmitted to the pump server. However, until institutions implement a Bar Code Medication Administration (BCMA) system and/or a Positive Patient Identification (PPID) system, the
physician order, which is housed on the pump server, could not be verified against the information programmed on the actual pump.

- Configuration 4 (displayed in the fourth column of Figure 21): Institutions could also have a configuration in which they have standardized concentrations/dosing units, wireless infrastructure, BCMA and/or PPID, when implementing smart pumps. Bar Code Medication Administration requires that dispensed medications be labeled with bar codes that are highly reliable for the medication administration process to proceed efficiently\textsuperscript{53}. Labels originate from both manufacturers of the medications and also through relabeling processes that are necessary to provide readily scanned labels on all dispensed items from the pharmacy. Institutions that do not have CPOE and PhIS but have wireless infrastructure and BCMA, could benefit from smart pumps in the following way: the nurse at the bedside uses the scanner on the smart pump (or a third party scanner) to scan the medication label. This information is sent wirelessly from the smart pump to the server. The pump server can then populate the smart pump parameters according to the information contained on the scanned medication label. The nurse would then review the entries and start the infusion.

The counterpart in identification to the Bar Code Medication Administration (BCMA) is Positive Patient Identification (PPID) through the use of bar coded armbands. Institutions that do not have CPOE and PhIS but have wireless infrastructure and PPID, could benefit from smart pumps in the following way: the nurse at the bedside uses the scanner on the smart pump (or a third party scanner) to scan the patient armband and the medication label (which also contains a bar code with the patient’s identification). This information is sent wirelessly from the smart pump to the server. The pump server verifies if the two pieces of patient identification (i.e., armband and medication label) match. If the two pieces of patient identification match, the pump allows the nurse to continue programming. Conversely, if a mismatch is detected, an alert is provided on the pump to warn the nurse of the error.

Thus, depending on the level of deployment of BCMA and/or PPID, different levels of benefits can be achieved. Although this configuration allows for a certain level of verification (e.g., synchronicity between patient information presented on medication label and patient armband), if institutions cannot verify the scanned information against a computerized physician entry or a pharmacy information system, there is still room for error.

- Configuration 5 (displayed in the fifth column of Figure 21): Institutions that have standardized concentrations/dosing units, wireless infrastructure, CPOE, PhIS, and BCMA/PPID, have a high probability of maximizing safe delivery of medications when implementing smart pumps. First, physician’s orders could be transmitted from CPOE to a smart pump server after being approved by pharmacy. The nurse at the bedside could use a scanner on the smart pump (or a third party scanner) to scan the patient’s armband, the medication label, and
his/her nursing badge (in the case where a third party scanner is used, the nurse would also scan the smart pump). This information would then be sent wirelessly from the smart pump to the pump server. The pump server, which is electronically linked to the CPOE, the PhIS, and/or the eMAR, would tether the administration to the medication order. If the scanned information matched the physician order, the pump server would populate the smart pump’s parameters according to the stored doctor’s orders. The nurse would then review the entries and start the infusion. Thus, depending on institutions’ level of deployment of BCMA and/or PPID, this configuration could allow for all “5 rights of medication” to be achieved.

- Configuration 6: (displayed in the sixth column of Figure 21): the sixth configuration which encompasses CPOE, PhIS, BCMA, PPID, and eMAR can allow for a complete closed-loop process when combined with smart pumps. This configuration is the same as the 5th configuration (see above) with the added benefit of the automated system transmitting the infusion with the associated clinician and patient identification to the electronic Medication Administration Record (eMAR) for automatic documentation of medication administration.

Figure 21: Summary of benefits achieved through integration of smart pumps with other incremental components of a fully integrated system.
In sum, although smart pumps alone may prevent programming errors, the main objective when implementing smart pumps is to introduce a technology that will help prevent all types of medication errors (i.e., wrong patient, wrong drug, wrong dose, wrong route, and wrong time). This objective can be achieved by following an informed incremental approach towards a fully closed-loop medication administration process.

**Key Recommendations:**

- Smart pumps should be integrated within the rest of the medication administration process to ensure their success and optimization.
- Smart pump implementation can follow an adaptable approach that allows incremental benefits while progressing towards a fully integrated system.
- When planning for smart pump acquisition, institutions should consider what other efforts could be conducted in parallel or sequentially to maximize the potential benefits of smart pump systems.
5.1.3 Understand key requisites to successful smart pump implementation to ensure optimal Return on Investment (ROI)

No matter what stage institutions are at in terms of achieving a fully-closed loop medication administration process, certain key requisites should be met when implementing smart pumps to ensure a Return on Investment (ROI).

Migrating from traditional to smart IV infusion pumps involves much more than simply replacing the pump. Despite the fact that the main purpose of smart pumps is to improve the safety of IV infusions, many hospitals convert to smart pumps primarily to replace their aging population of traditional pumps. This asynchrony between hospitals’ main motivation and the pumps’ main purpose significantly impact how hospitals approach the migration process. Consequently, they do not follow a formal process and the safety benefits of smart pumps are not fully realized.
Three key requisites should be considered when planning for successful implementation of smart pumps to optimize institutions’ return on investment. Figure 22 below describes the various effects (in terms of safety and ROI) of addressing, or not addressing, the following requisites:

1. Standardize the drug concentrations and dosing units. If thoughtful time and effort is not devoted to this step, nurses will inevitably get frustrated because their practice will not be adequately reflected in the drug library. Consequently, institutions will have a negative ROI as nurses will not use the pumps’ Dose Error Reduction System (DERS) but rather, they will use the generic infusion mode which has no safeguards.

2. When evaluating smart pump products, institutions must pay careful attention to selection of a pump which encourages users to enter the DERS. Institutions must prepare to promote a culture of safety where it is not an option to bypass the DERS and implement a policy to re-enforce this rule. Pump designs that don’t encourage users to enter the DERS should be avoided because users will be more likely to bypass the safety system of the pump by programming in the generic mode, thereby leading to a negative ROI.

3. Prior to implementing smart pumps, institutions must be aware of, and prepare for, the major cultural shift that is needed in nursing to achieve reduction in medication administration errors. The migration from traditional IV infusion pumps to smart infusion systems brings about changes to practice in nursing and in pharmacy. For example, because smart infusion systems require the standard concentration platform, there may be changes in who mixes the drugs (i.e., shift from nursing to pharmacy). Furthermore, the steps involved in programming a smart pump differ from those involved in programming a traditional pump (see Figure 23 for an example of the differences between programming a traditional pump vs. a smart pump). For example, when programming a continuous infusion on a traditional pump, nurses simply enter the flow rate and volume to be infused. When programming a continuous infusion on a smart pump, however, nurses must complete the following steps: first select a clinical care area, then select a drug name and concentration from a predefined set of concentrations, and lastly they can enter either (a) the dose rate and volume to be infused or (b) the flow rate and volume to be infused. One noteworthy difference is that smart pumps can eliminate the need to convert dose rate units (e.g., mg/hr) into flow rate units (e.g., ml/hr). Typically, physician orders are given in dose rate units. Therefore, when using traditional pumps, nurses are required to perform conversion calculations (i.e., convert dose rate into flow rate) and this often leads to errors. Instinctively, it would seem that elimination of the need to perform mathematical conversions would appeal to nurses. The reality, however, is that nurses are so accustomed to thinking in terms of flow rate, that it is a huge cultural shift for them to think in terms of dose rate. Consequently, when nurses are introduced to smart pumps, they continue to enter flow rate (and continue to make conversion errors) even though they could simply enter the dose rate provided on the physician order.

Thus, prior to introducing smart pumps, institutions must promote a culture of safety which encourages nurses to use the technology in the safest way possible. It is not enough to simply implement the new technology and expect nurses to
change their regular workflow. Efforts must be put in place to help nurses migrate from one technology to the next in the safest way possible.

Figure 22: Key requisites to successful smart pump implementation to ensure optimal Return on Investment (ROI)
In sum, it is essential to identify at the outset the requisites to successful implementation of smart pump systems. Smart infusion systems will have their greatest impact and will optimize ROI if (1) there is synchronicity of information (e.g., standard concentrations) across the various system components (e.g., CPOE, PhIS, pump library); (2) they are designed to encourage users to follow the safest path (e.g., pump encourages entry into dose error reduction system); and (3) efforts are made to address the cultural shift (e.g., think in terms of dose rate rather than flow rate) that implementation of smart pump systems creates.

**Key Recommendations:**
- Standardized concentrations and dosing units must be established prior to smart pump implementation to maximize ROI.
- Pump designs must encourage entry into DERS and institutions must mandate use of DERS to ensure ROI.
- Institutions must prepare nurses for cultural shift of having to think in terms of dose rate rather than flow rate. Institutions should encourage this shift as it reduces the need for mathematical conversions; thereby enhancing patient safety.
5.1.4 Formation of multi-disciplinary steering committee

The key to a successful implementation of a smart pump system is to view the change as an institutional undertaking as opposed to a departmental undertaking. As such, a project manager should be appointed to ensure that the plan is being monitored and updated as necessary with feedback to upper management on a regular basis. Representatives from pharmacy, nursing or biomedical engineering are generally recommended as a project manager given their central roles in the migration process.\textsuperscript{11,18}
The first task of the project manager is to gain an appreciation for the impact that smart IV infusion pumps will have on all potential stakeholders, and to form a multi-disciplinary steering committee. By understanding the impact that smart pumps can have on various stakeholders’ workflow, the project manager will be well positioned to convince the steering committee of the value of the smart pump system. Consequently, all steering committee members will be able to help define and champion the migration from traditional to smart pumps. In developing a migration approach for smart pump systems, there are many decisions that require the input of an interdisciplinary team. Formation of a multi-disciplinary steering committee is imperative to success and should include expertise in disciplines including the following:\(^{11,18,40}\):

- **Nursing**: help identify what problems currently exist and understand what solutions best address end-user needs
- **Physicians**: understand prescribing styles for multiple dosing units
- **IT**: understand server and interface needs, and wireless infrastructure
- **Biomedical engineering**: understand technical performance and support considerations
- **Pharmacists**: help design drug libraries

Optimized smart pump adoption requires the creation, customization and maintenance of drug libraries for different clinical care settings. In the early planning stages, the project manager should establish workgroups for each Clinical Care Area (CCA) to gather support and input from each clinical service line involved in infusion therapy\(^{54}\).

The second task of the project manager should be to develop a project charter that has the buy-in of the steering committee. The migration from traditional pumps to a smart infusion pump system has many steps and involves actions on the parts of all the major stakeholders. The project charter is key to establishing the scope of the project, and keeping the steering committee moving in the same direction. Thus, the project manager should ensure to have a complete, written, approved, and funded plan that has buy-in from all the major stakeholders. Finally, agreed-upon objectives should be time-specific and measurable\(^{55}\).

**Key Recommendations:**

- Institutions should appoint a Project Manager.
- Project Manager must form a multi-disciplinary steering committee including expertise in nursing, pharmacy, medicine, IT, and biomedical engineering.
- Given that drug libraries must be created for each Clinical Care Area (CCA), the Project Manager should also establish workgroups for each CCA.
5.2 Smart Pump System Evaluation and Acquisition

5.2.1 Conduct a User Needs Assessment (UNA)

A User Needs Assessment (UNA) is a process of identifying key stakeholders and discovering and assessing the needs of all stakeholders. A UNA helps ensure that institutions assemble a multidisciplinary team that ensures (1) communication with all stakeholders in the medication administration process, (2) the infrastructure for safe technology implementation, (3) effective maintenance after implementation. A UNA will identify the required features, functions, and safety criteria that each pump product will be measured against based on an in-depth analysis of the user environment and tasks.

The first step in the UNA is to assemble members of the steering committee (see Section 5.1.4 above) as they should all be involved in the evaluation and acquisition of smart pump systems. As with most medical systems, evaluation and acquisition of smart pump systems present several risks to healthcare organizations and require expertise from multiple disciplines to make informed decisions. Systems that fail to consider the capabilities and limitations of their users can result in human error, potentially leading to adverse events. Similarly, systems that do not meet functional and system integration requirements have associated adoption risks as they can hinder an institution’s ability to provide efficient care. Thus, involvement of the steering committee is imperative to minimizing risks associated with the selection of a smart pump system.

The second step involves establishing a comprehensive set of requirements that potential smart pump products will be measured against. Specifically, functional and usability requirements for pump units, tubing sets, DERS, IT capabilities and associated software tools should be established. ECRI Institute’s annual review of currently available smart infusion systems provides a good starting point for identifying available smart pump systems and understanding the differences between them. The steering committee should also consult other institutions that have worked with the devices under consideration to gain different perspectives on the products. Furthermore, institutions must identify their own unique needs and translate them into requirements. Every healthcare institution has a set of unique needs depending on various factors including the physical design of the facility, patient populations, types of medications used, and IT infrastructure. Therefore, a smart infusion system that is suitable for one institution may not be suitable for another institution. Thus, institutions should identify the needs of their end users and those arising from their work environment prior to product evaluation.
Key Recommendations:
- Steering committee should conduct a User Needs Analysis (UNA) to identify criteria that each pump product will be measured against.
- Criteria should address behavioural and functional requirements.

5.2.2 Issue a Request for Proposal (RFP)

The Request for Proposal (RFP) should specify the comprehensive list of requirements identified in the UNA \(^7,58\) (see section 5.2.1 above). Consider requesting the following in the RFP:

- A full in-service of the current technology to get a feel for the services and cooperation that a vendor provides both before and after implementation\(^56\). This is an important consideration given that the purchase will lead to a long term relationship with the chosen vendor.
- Presentation of vendor system’s future capabilities.
- Independent Human Factors product evaluation

Key Recommendation:
- Request for Proposal (RFP) should call for full in-service of vendors’ technology.

5.2.3 Conduct in-depth product evaluation

The steering committee should evaluate responses to RFP against the minimum requirements set-out in the RFP, and potential products should be shortlisted for further evaluation.

There are many variations in the functionality and ease of use of both the pump and the software across suppliers. Therefore, when evaluating the shortlisted products, the steering committee must assess all components of smart infusion systems (e.g., drug library software, continuous quality improvement software) rather than solely focus on the pumps themselves. There are many ways in which information can be categorized, and some suppliers offer better standard reports (that include CQI data of most interest to hospitals) than others. Given that different stakeholders use different smart pump system components (e.g., nurses use pump, pharmacists use drug library software, and risk management use continuous quality improvement software), all members of the steering committee should attend product evaluation meetings to ensure that all functional and system integration requirements are considered. Thus, institutions must establish a set of criteria for evaluating the vendors and gather information accordingly. A good starting point for setting such criteria and learning about vendors’ support quality is the KLAS Enterprises’ report on smart infusion systems\(^59\).

The steering committee should also assess the extent to which vendors’ vision and future plans, with respect to a fully integrated smart infusion system (e.g., bar coded
medication administration system, real-time vital sign monitoring), corresponds to their own progressive approach towards a fully integrated system.

Knowledge gained during this phase will result in an understanding of which vendors meet the healthcare institutions’ needs from a time, cost, and future vision/partnership perspective.

**Key Recommendations:**
- All components of smart pump system (including drug library and continuous quality improvement software) must be evaluated as some suppliers offer better standard reports than others.
- Representative from all disciplines (e.g., nursing, pharmacy, IT, biomedical engineering, risk management) must attend evaluation meetings to ensure all functional and system integration requirements are considered.

### 5.2.4 Conduct Human Factors evaluation

A healthcare organization’s procurement process provides an opportunity to evaluate medical technology from a Human Factors perspective to enhance its safety and efficiency. In 2004, Health Canada issued a notice recommending that hospitals perform a Human Factors evaluation prior to selecting a pump, to reduce the major safety concerns associated with infusion pumps.

The following two Human Factors evaluation methods are recommended:

1. A Heuristic Evaluation of each pump: Refers to the systematic inspection of a user interface design for usability. Using a checklist of usability principles (or heuristics) as a guide, each screen of the interface and aspect of the hardware is evaluated according to how well it satisfies each principle.
2. User testing: Refers to an observational technique in which representative end users perform realistic scenarios in a simulated environment to assess the appropriateness and ease of use of a system prior to its introduction into the real world.

**Key Recommendations:**
- Human Factors evaluation should be conducted.
- Performance of heuristic evaluation and usability testing are highly recommended to ensure appropriateness and ease of use of selected smart pump.

### 5.2.5 Acquisition

Based on the results of the in-depth product evaluations and the Human Factors evaluations, the steering committee should select a preferred product. Then, the
committee should work with the institution’s purchasing department or group and the vendor to negotiate and award the contract.

**Key Recommendation:**
- Steering committee must work with institution’s finance department and the selected vendor to negotiate award and contract.

### 5.3 Drug Library Development

The next step in getting ready for implementation is to (1) develop standardized concentrations and dosing limits (e.g., mcg/min vs. mcg/kg/min), (2) create drug library subsets, (3) set dosing limits, and (4) consider implementing clinical advisories.

#### 5.3.1 Develop hospital-wide standardized concentrations and dosing units

Standardization of high-risk IV drug concentrations and dosage units, within and across all hospital departments involved in the medication administration process, is essential to reducing the probability of adverse drug events. Researchers have shown that lack of standardization of drug concentrations and dosing units contributes to fatal overdoses. For example, if a “unit/kg/hr” dosage unit is inadvertently selected instead of a “units/hr” dosage unit, a 70 kg patient could receive a 70 fold overdose.

Confusion around multiple concentrations and dosing units has been identified as a frequent contributor to medication errors. This problem is compounded by the fact that both nurses and patients regularly transfer among various clinical care areas. Thus, although there will always be some degree of variability in clinical practice given the inherent variability in patient needs, hospitals must strive to reduce unnecessary variability.

Furthermore, as discussed in section 5.1.1 above, successful adoption of smart pump technology is dependent on integration of standardization of concentrations and dosing units into the pumps’ drug libraries. Standardization maximizes smart pump safety in many ways including the following:

- Simplifies medication ordering and allows for synchrony between information provided on physician order and information contained in pump library.
- Reduces the need to perform calculations, reducing risk of conversion errors.
- Fewer concentrations are prepared as the number of individualized concentration diminish; thereby reducing the opportunities to make incorrect selection on pump.

The following is a list of steps that should be followed when developing hospital-wide standardized concentrations and dosing units:
1. Obtain management support as the development of hospital-wide standardized concentrations and dosing units requires top-level decisions. Therefore, the first step is to assemble individuals to form a Standardization Task Force Team comprised of key stakeholders from all levels of the medication administration process (i.e., physicians, pharmacists, and nurses).

2. Once the Standardization Task Force Team has been formed, create a plan with clear, time-specific, and measurable goals.

3. Obtain a hospital-wide inventory of medication concentrations and dosage units.

4. Identify variations in the current practice. For each clinical care area, identify the drugs that require standardization.

5. Members of the Standardization Task Force Team must work together to establish an agreed-upon list of standardized concentrations and dosing units for all IV medications (begin with most common IV medications).
   - Care must be taken to limit the number of concentrations for a given drug as the likelihood of selection errors increases with the number of different concentrations available in the physician order entry system and/or the drug library.

6. All stakeholders (physicians, pharmacists, and nurses) agree upon the consolidated list of drug concentrations and dosing units. Members of the Standardization Task Force Team must also agree on the implementation date/time of the new standards.

7. Ensure standardization of drug nomenclature across medication administration components. Drug nomenclature must be consistent with what appears on CPOE, PhIS, eMAR and other IT systems used in the institution. Institutions that do not have CPOE or eMAR must identify preprinted orders and documentation forms that require updates to prevent conflicts in description of drug products and dosage units.

8. Establish a formalized process to ensure that any changes made to the agreed-upon standardized list are reflected throughout all medication administration systems. For example, if a pharmacist makes a change to a drug concentration contained in the smart pump drug library, this change should also be made in the physician ordering system. Necessary updates may require involvement of IT or dedicated committees to synchronize CPOE, PhIS, eMAR, PPID, and other IT systems. Institutions that do not have CPOE or eMAR must identify preprinted orders and documentation forms that require updates to prevent conflicts in drug concentrations and dosage units. It is crucial that a synchronization process be put in place as changes to the agreed-upon list are inevitable.
9. The Standardization Task Force Team must also identify any policies and/or IV medication guidelines that require updating as a result of the changes that standardization instigates on the medication administration system.

**Key Recommendations:**
- A Standardization Task Force committee should be formed.
- Hospital-wide inventory of medication concentrations and dosage units should be obtained.
- The Standardization Task Force must establish a list of standardized concentrations and dosage units for all medications.
- A formalized process should be established to ensure changes to standardized list are reflected throughout all medication administration systems.
- Policies and guidelines must be updated according to changes made to standardized list.

5.3.2 Create drug library subsets

As discussed in Section 5.1.4 above, in the early planning stages, the project manager should have established workgroups for each Clinical Care Area (CCA) to gather support and input from each clinical service line involved in infusion therapy\(^{54}\). Optimized smart pump adoption requires the creation, customization and maintenance of drug libraries for different clinical care settings to create library subsets for specific groups of patients\(^{40}\). The creation of such CCA specific library subsets will help institutions deal with large dose ranges. For example, higher limits can be set for drugs used in the anesthesia unit compared to drugs used in the intensive care unit for ventilated patients. It is highly recommended that patients be grouped by populations that require similar medications (e.g., critical care patients vs. medical/surgical patients). For neonatal and pediatric patients, weight groupings are suggested (e.g., less than 5 kg vs. 5-40 kg vs. greater than 40 kg). Thus, it is imperative that institutions recognize that development of a one-size-fits-all drug library is not beneficial\(^{54,56}\).

Once a list of agreed-upon standardized concentrations and dosing units for all IV medications has been established, it should be sent to each CCA workgroup who will set dosing limits accordingly.

**Key Recommendations:**
- Clinical Care Area (CCA) specific drug library subsets must be created.
- Drug library subsets should be grouped by patient populations that require similar medications. Neonatal and pediatric patients should be grouped by weight.

5.3.3 Set dosing limits

Each Clinical Care Area (CCA) workgroup must develop dosage limits for their patient population. First, dosage limits must be set for different types of infusions (e.g.,
continuous, intermittent, bolus) on the basis of current policy, practice, and consensus among each CCA workgroup. It is especially important to set separate entries in the drug library for bolus and maintenance drug administrations. If not, dosing limits will be set high to accommodate bolus rates, and the protection of maintenance rates will be circumvented. Second, when considering dosage limits, workgroups must decide which dose limits require a hard limit (displays alert that cannot be overridden) versus a soft limit (displays an alert that can be overridden). Finally, CCA workgroups must also set limits around non-standard entries which occur when individualized medication dosing needs must be entered by the nurse. Non-standard entries (i.e., nurse manually enters the concentration) are more error-prone than standard entries (i.e., nurse selects from a list of standardized concentrations) as they require extra data entries on the smart pump.

Furthermore, it is difficult to set effective limits for non-standard entries as they require wide dosing ranges given that the limits are not associated with a given concentration but rather, they are solely associated to a drug name.

When determining dose limits, CCA workgroups should consider how to prevent infusion errors that commonly occur with traditional (non-smart) pumps. For example, dosing limits should be set to prevent multiple of ten errors and push button errors (e.g., 10 fold overdose errors). Furthermore, given that current smart pump drug libraries have the capacity to hold large datasets, they allow for drug selection by therapeutic condition (i.e., allow multiple listings of the same drug for different patient conditions). For example tPA ((Activase®, Alteplase, recombinant) may be listed as: tPA-stroke; tPA-MI (Myocardial Infarction); and tPA-PE (Pulmonary Embolism) with corresponding concentrations, dosing units, and limits appropriate for each condition. Having multiple listings of the same drug for different patient conditions permits establishment of narrow therapeutic windows because limits can be tightened according to patient conditions. However, this approach also increases the risk of selection errors. That is, when using a smart pump, a nurse may inadvertently select the wrong drug listing and consequently not be provided with accurate dose limits for the patient’s condition. Thus, CCA workgroups must be aware of the various trade-offs associated with setting dose limits and determine which approach works best for their given population. Once CCA workgroups have reviewed the drug dosing guidelines for each medication included in their drug library, they must establish protocols for each.

**Key Recommendations:**

- Dosage limits must be set for different types of infusions, especially for bolus vs. maintenance drug administrations.
- Both soft and hard limits must be set.
- Protocols must be established for each dosing guideline.

### 5.3.4 Consider implementing clinical advisories

Smart infusion systems will have their greatest impact if they help link pieces of information (e.g., information contained within physician orders and drug libraries) and if they alleviate repetitive tasks (e.g., checks for problems). Smart infusion pump systems can improve the medication administration process by harnessing the strengths of
information technology (e.g., remembering what rules apply for dosing limits) and freeing up clinicians cognitive resources to allow them to do what they do best (e.g., think critically about whether other treatments are needed).\textsuperscript{11}

During critical situations, clinicians require a clear view of clinically significant information. Most smart infusion systems have the capability of displaying short messages (referred to as “clinical advisories”) to alert clinicians of special instructions, precautions or warnings related to a drug administration. Clinical advisories can be used to synthesize information and notify clinicians of important patient issues. Currently, clinical advisories can outline administration techniques, recommend monitoring and other drug-related information, e.g., (“administer only through central line”), notify nurses that something is wrong with an order, as well as support specific hospital policies. Future integration of smart pumps with CPOE, real-time vital sign alerts or laboratory results hold promise for improving the safety benefits of clinical advisories.\textsuperscript{7} Thus, while clinical advisories can increase compliance with regulatory protocols, their ability to reduce medical errors will be greatly enhanced with an automated closed-loop medication administration system.

For clinical advisories to be useful, users must acknowledge the alert. Researchers\textsuperscript{40,9,41} have shown that clinicians often override soft limit alerts. Therefore, although soft limits and clinical advisories can be beneficial, they can negate the benefits of having a smart pump if clinicians simply ignore the alerts. Studies have shown that clinicians bypass the safety features of other technologies as well. For example, it has been reported that drug safety alerts on Computerized Physician Order Entry (CPOE) systems are overridden by clinicians in 49\% to 96\% of instances.\textsuperscript{48} Efforts must be made to increase the relevance and correct use of alerts without burdening clinicians. If thresholds for sending clinical advisories are too low, nurses may develop alert fatigue, which can lead to overriding important alerts.

Clinicians should not view the dose-checking feature of smart pumps and the clinical advisories as options that can be ignored or bypassed without serious consideration. Compliance with the technology should be measured and any barriers should be identified and removed. The following is a list of recommendations to improve medication safety alerts:

- Reduce the proportion high severity alerts
- Prioritize a subset of high-severity alerts and only permit these alerts to interrupt workflow
- Consider customizing alerts depending on the clinician’s specialty
- Update clinical advisories on a regular basis to avoid alert fatigue. If users continuously read the same alert, they will eventually get in the habit of ignoring all alerts.
Key Recommendations:

- Institutions should consider the use of clinical advisories to synthesize information and notify clinicians of important issues.
- Clinical advisories must be highly relevant and should be used infrequently to reduce “alert fatigue”.
- Usefulness of clinical advisories will be greatly enhanced when institutions have a fully automated medication administration system.

5.4 Configuration and Implementation Planning

To gain maximum clinician acceptance of smart pump systems, members of the multi-disciplinary steering committee (see section 5.1.4 above) must work together to reinforce the momentum of the smart pump implementation project. Steering committee members must communicate the imminent implementation of the smart pump system to all stakeholders (nursing, pharmacy, physicians, IT, and biomedical engineering). All stakeholders should (1) have a clear understanding of the new smart pump functionality, (2) be committed to adopting the system, and (3) have a good appreciation of the effects this integration will have on their workflow. These latter three objectives can be respectively achieved through training and policy development, creating a culture of safety, and performing a risk analysis.

5.4.1 Training/ policy development

5.4.1.1 Training

Successful implementation and adoption of smart pumps is dependent on training. In planning training, organizations must consider the technical skills required for adopting the new smart pump system, while also addressing motivational issues. The technical skills can be obtained through courses offered by vendors, or an internal training department. Motivational issues, however, include potential resistance to change. The key challenge is convincing clinicians of the pump’s value. Poor first impressions can reduce attendance at in-service training and decrease probability of compliance. Therefore, institutions must ensure that all end-users have a clear understanding of (a) the rationale for the migration from traditional pumps to smart pumps, and (b) the potential benefits to using the new technology. Thus, training is important, and should encompass both technology and organizational aspects.
Table 9 presents suggestions to facilitate training:

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<tr>
<th>Key Challenges</th>
<th>Suggested Activities and Tasks</th>
</tr>
</thead>
</table>
| Overcoming resistance to new pump technology             | • Form a smart pump training team, dedicated to issues surrounding the education and awareness of the incoming smart pumps.  
• Clearly show how DERS can reduce programming errors (e.g., present a realistic scenario and/or video evidence from usability testing) to get clinicians on board  
• Ensure clinicians understand the role of smart pumps as a patient safety tool rather than solely as an infusion tool. |
| Maximizing attendance at training sessions and facilitate retention of pump training | • Establish a continuous training campaign in all pilot areas prior to implementation.  
• Distribute practice pumps to allow nurse familiarity  
• Facilitate nurse attendance by holding training sessions in locations near the nursing units.  
• Post tip sheets throughout clinical care areas on how to use pumps.  
• Identify project evangelists to boost nurse buy-in  
• Conduct training sessions close to implementation day to optimize retention.  
• Mandate hands-on training for all nurses. |

Table 9: List of key challenges associated with pump training and suggested activities to overcome these challenges.

One-time training will likely not be sufficient. Therefore, institutions should put in place a process for verifying competency in using the pump and monitoring compliance once the smart pumps have been implemented. Specifically, nurse super-users (nurses who received initial intensive training on the use of the new pump to be able to teach other users) should be appointed to guide pump implementation and coordinate training and troubleshooting post-implementation.

5.4.1.2 Policy development

Ongoing communication and education about new processes and policies with regards to use of smart pump is imperative. For example, protocols around overriding dosing alerts and/or clinical advisories should be developed, and highlighted during pump training. Furthermore, institutions must ensure that all process guidelines and training resources be updated to reflect these new processes and associated protocols.

In sum, when planning for implementation, institutions must understand and address both the technological and behavioural changes that smart pump implementation incur. Furthermore, a post-implementation follow-up plan must be put in place to ensure compliance and optimize smart pump benefits.
**Key Recommendations:**

- Training should address technical and behavioural factors affecting effective use of technology and user acceptance.
- A process should be in place to coordinate training and troubleshoot post-implementation.
- Institutions should establish ongoing communication and education about new processes and policies regarding smart pump use.

### 5.4.2 Creation of a culture of safety

Institutions must recognize that training and protocol development are not sufficient for ensuring smart pump adoption\(^{49}\). For end-users to adopt the new technology, they must buy-into the idea that the technology will improve safety. Therefore, institutions must present introduction of smart pump systems as a safety enhancing initiative rather than a pump replacement initiative.

Institutions must promote a culture of safety around smart pump use by:

1. Promoting the critical thinking necessary to (a) evaluate alerts from a clinical and safety perspective and (b) limit overrides to situations that have been duly assessed\(^ {49} \).
2. Providing a medium for all end-users to express their concerns, and report conditions that do not support best practice and encourage or necessitate work-arounds\(^ {49,56} \).

**Key Recommendation:**

- Institutions must promote a culture of safety urging nurses to evaluate alerts and limit overrides to circumstances that have been fully thought out.

### 5.4.3 Risk analysis: consider effects of smart pump integration on existing medication administration processes

Traditionally, the process for implementing standard intravenous pump technology was straightforward as it had little impact on the rest of the medication delivery process. That is, the implementation process consisted primarily of placing the chosen product into a specific environment and training nurses on the technical aspects of the pump. The implementation process for smart pump technology, however, is more complex and has a larger impact on the medication process. Specifically, implementation of smart pump systems requires substantial process changes which impact nursing as well as other stakeholders involved in the medication administration process\(^ {56,67} \).

Process changes required as a result of smart pump implementation include the following:
• Given that smart infusion systems require the standard concentration platform, there may be changes in who mixes the drugs (i.e., shift from nursing to pharmacy).

• Implementation of smart pump systems require changes to standardized IV drug concentration for continuous and intermittent infusions, allowing nurses to program the dose rather than just the flow rate.\textsuperscript{67}

• The use of smart pumps in combination with standardized concentrations can shift the calculation burden from nurses and pharmacists to computers. That is, drug libraries within the smart pump automatically default the appropriate concentration and measurement units (e.g., mg/hr) when the medication is selected, which eliminates the need to perform unit conversions (e.g., convert a dose into a rate). However, given that nurses are accustomed to entering rate (e.g., ml/hr), they will require support and guidance in shifting from thinking in terms of rate to thinking in terms of dose (see section 5.1.3 for more details).

Furthermore, process changes resulting from smart pump implementation can lead to unanticipated new sources of error. Examples of such unanticipated sources of error include the following:

• Changes in drug concentrations can result in errors committed by pharmacists. For example, pharmacy could send a concentration of 4mg/250ml although hospital policy and pump parameters dictate 4mg/500ml. If the error is undetected by the nurse, s/he could easily mis-program the pump.\textsuperscript{49,67}

• While traditional pumps required nurses to enter rate and volume, smart pumps require extra steps such as selection of drug name and concentration. These extra steps can introduce new sources of error such as inadvertently selecting the wrong drug, or the wrong unit of measure in smart pump drug library.\textsuperscript{49,67}

Whenever possible, institutions should consider conducting a Failure Modes and Effects Analysis (FMEA) to help understand the potential new sources of error that can occur as a result of workflow changes.\textsuperscript{67} An FMEA is a method to analyze potential problems with the new workflow, making it easier mitigate such issues.\textsuperscript{67}

As mentioned in section 5.3.1 above, institutions must establish a formalized process to ensure that any changes made to information that is shared across different stakeholders (e.g., physicians and pharmacist) are reflected throughout the corresponding departments.
Key Recommendations:

- Institutions must identify (1) process changes that will result as a consequence of smart pump implementation, and (2) new errors that could result as a function of the process changes.
- Institutions must establish a formal process to ensure that changes made to information that is shared across multiple stakeholders are reflected throughout the corresponding departments.

5.5 Go-Live (implementation)

Provided that significant time and effort has already gone into ensuring synchronization amongst physician, pharmacy and nursing information systems, institutions should be ready to upload the drug library on all pumps. If manual upload of data set is required, institutions must locate all smart pumps. If the upload is done wirelessly, institutions should test the (a) integrity of both the dataset updating functionality and the wireless system, and (b) the scope of coverage.

Key Recommendation:

- Drug libraries must be uploaded on all pumps. If manual upload is required, institution must ensure that sufficient resources are available to locate all pumps. If upload is done wirelessly, institutions should test dataset updating functionality and scope of coverage.

5.6 Operation and Maintenance/Monitoring

The main purpose of smart pumps is to improve the safety of IV infusions. Specifically, smart pumps contain dose-checking technology (i.e., drug libraries) to help clinicians avoid potentially harmful infusion-related medication errors. However, to take full advantage of smart pump error prevention potential, the clinician must use the technology in a consistent and proper manner. Therefore, to ensure safety benefits of smart pumps, institutions must ensure compliance with use of the dose-checking technology.
Although the most important element of successful adoption is to follow-up to assess compliance, it is often the element that is left to drift. Lack of sufficient follow-up can negate all earlier efforts as end-users may revert to their old ways. Regarding smart pumps, this could result in nurses electing to bypass the dose-checking technology and using the pump in its standard rate-based mode. Thus, compliance with technology should be assessed and barriers to successful adoption should be identified and removed.

### 5.6.1 Drug library updates

Drug libraries must be updated on a regular basis to ensure that information contained in the pumps match the physician orders. When drug libraries are outdated and do not match the orders, nurses bypass the drug library and program in the basic infusion mode.

Wireless infrastructure greatly facilitates drug library updating (see section 5.1.1 above for more details). That is, with wireless communication, every pump that is plugged into a power outlet (not just running on battery), automatically receives the update. The pump notifies the user of the availability of a new library and the user can accept the update when the pump has finished an ongoing infusion. Institutions that do not have wireless infrastructure, however, will not be able to update drug libraries on a regular basis as they require either a mobile server or manual upload.

**Key Recommendations:**
- Drug libraries must be updated on a regular basis to ensure compliance.
- Wireless infrastructure is necessary for regular CQI downloads and drug library uploads.

### 5.6.2 Continuous quality improvement

Most smart pump vendors provide continuous quality improvement (CQI) software which automatically collects data that can be used to assess drug library compliance. The software's CQI logs automatically document every alert, the medication involved, initial dose programmed, and the subsequent action by the caregiver. Furthermore, the logs document the patient care area or patient type, location, time, and date. When the patient-identification option is implemented (e.g., when used in conjunction with bar coding), the logs can also capture patient-specific events.

Although a major feature of smart pumps is their ability to log the entry of pump settings for CQI analysis, CQI data analysis software is still very immature and difficult to use. Therefore, despite the fact that smart pump vendor’s provide “canned reports”, institutions will still need to allocate significant time and effort into CQI data analysis to produce quality reports. The major challenge that most healthcare institutions face when it comes to CQI data analysis is the lack of patient contextual information. The problem is that currently, all manufacturers require Positive Patient Identification (PPID) to access patient contextual CQI data. Given that most hospitals do not yet have PPID functionality, they are limited in how they can use the CQI data. Thus, although smart pump vendors will boast that data gathered by smart pumps provides an effective way to
mine data for quality improvement, the reality is that data mining for quality improvement is not a trivial task and will require significant ongoing time and effort.

Continuous Quality Improvement logs provide massive amounts of data that can be mined for quality improvement. Access to all this data, however, can be overwhelming, especially for nurses or pharmacists who do not have the skills or time to analyze the data. Consequently, CQI data often goes untouched. Therefore, institutions must designate the task of CQI data analysis to specific individuals and provide them with the necessary training to carry-out the task. It is highly recommended that the CQI data analysis task be assigned to individuals from each clinical care area to ensure they have the contextual knowledge to understand the data. CQI data analysts should be encouraged to enlist the help of (a) pharmacists to help with the analysis, and (b) risk management to help disseminate the findings. Publicizing salient examples of “good catches” to end-users can help underscore the utility of drug libraries.49

When hospitals first analyze their CQI data, they are often surprised by the high frequency of alerts that result in overrides. An override, which can only follow a "soft" alert, indicates that an alert was bypassed by the clinician. Overrides can result from dose-limit alerts that have been set too low, but more frequently overrides represent a discrepancy between a hospital's best practice guidelines and nurses’ current practice. That is, nurses do not perceive the override to be dangerous, and thus current practice prevails over new best practices.54

Institutions that do not have wireless infrastructure will not be able to mine data for quality improvement as this would require too much time to manually download data by connecting a laptop computer to each pump. At best, these institutions can expect to mine CQI data every six months or once a year.

In sum, it is not sufficient to purchase smart pumps, program the drug library once, train users and hope that the drug library features will be used effectively. Institutions (with wireless capability) must prepare to maintain their systems by collecting and reviewing log analysis data, and updating the drug library on a regular basis.49 Until institutions integrate PPID, the usefulness of the CQI data will be limited as it will lack contextual information needed to fully interpret the data.

Figure 24 below illustrates the maintenance (i.e., drug library updates) and monitoring (i.e., CQI analysis) capabilities as a function of (1) whether or not institutions have wireless infrastructure and (2) whether or not hospitals have Positive Patient Identification (PPID). Specifically, if hospitals do not have wireless and do not have PPID (bottom left quadrant), they will have infrequent drug library updates and their CQI data will be of limited usefulness. If, however, institutions have wireless capability and PPID (upper right quadrant), they can frequently update their drug library, and their CQI data will be highly useful. Thus, wireless and PPID capability greatly enhance institutions monitoring and maintenance capabilities.
Figure 24: Maintenance (i.e., drug library updates) and monitoring (CQI analysis) capabilities as a function of (1) whether or not institutions have wireless infrastructure and (2) whether or not hospitals have Positive Patient Identification (PPID).

<table>
<thead>
<tr>
<th>Wireless</th>
<th>PPID</th>
<th>CQI data</th>
<th>Drug library</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>Limited usefulness</td>
<td>Infrequent updates</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Very useful</td>
<td>Readily accessible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wireless</th>
<th>PPID</th>
<th>CQI data</th>
<th>Drug library</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>Limited usefulness</td>
<td>Infrequent updates</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Very useful</td>
<td>Readily accessible</td>
</tr>
</tbody>
</table>

**Key Recommendations:**
- Institutions must assess drug library compliance, and remove barriers to adoption.
- Continuous Quality Improvement (CQI) data can be used to assess drug library compliance.
- Without patient identification capability (e.g., through bar coding), CQI data lacks useful contextual information.
- All vendors’ CQI data analysis software is still immature and difficult to use.
- Institutions must be aware that they will need to allocate significant time and resources into CQI data analysis to produce quality reports.
- Institutions must assign the task of analyzing CQI data to specific individuals and provide them with necessary training.
- Ideally, CQI data analysis should specific to each Clinical Care Area (CCA), and thus, should be conducted by individuals from each CCA.
**Rate Yourself**

Establish where you fit within the following diagram to identify the achievable frequency of drug library updates and usefulness/accessibility of CQI data.

<table>
<thead>
<tr>
<th>Wireless</th>
<th>PPID</th>
<th>CQI data: Very useful</th>
<th>Drug library: In frequent updates</th>
<th>CQI data: Very useful</th>
<th>Drug library: Frequent updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
<td>Limited accessibility</td>
<td></td>
<td></td>
<td>Readily accessible</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>Limited usefulness</td>
<td>Limited accessibility</td>
<td></td>
<td>Readily accessible</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Limited usefulness</td>
<td>Limited accessibility</td>
<td></td>
<td>Readily accessible</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Moderate usefulness</td>
<td>Frequent updates</td>
<td></td>
<td>Readily accessible</td>
</tr>
</tbody>
</table>

PPID: Positive patient identification
CQI data: Continuous quality improvement data
6 Current Status of Ontario Smart Pump Adopters in Relation to Key Recommendations for Successful Migration

The following section presents a summary of the current state of Ontario smart pump adopters as they relate to the key recommendations for successful migration presented in section 5 above. Data from the field study results (section 4 above) were used to assess Ontario smart pump adopters’ adherence to the key requisites to successful implementation.

6.1.1 Current status of Ontario smart pump adopters in relation to the benefits achieved through integration of smart pumps with other components of the fully integrated medication administration system

Figure 25 illustrates the current status of Ontario smart pump adopters in relation to the benefits achieved through integration of smart pumps with other components of the fully integrated medication administration system. As highlighted on Figure 25, all Ontario smart pump adopters have both standardized concentrations and PhIS. Furthermore, four of these hospitals have the added benefit of wireless capability which allows for frequent drug library updates and CQI data transfers.

Figure 25: Current status of Ontario smart pump adopters in relation to the benefits achieved through integration of smart pumps with other components of the fully integrated medication administration system.
6.1.2 Current status of Ontario smart pump adopters in relation to their adherence to “key requisites to successful smart pump implementation”

Figure 26 illustrates the current status of Ontario smart pump adopters in relation to their adherence to “key requisites to successful smart pump implementation” to ensure optimal Return On Investment (ROI). As indicated at the bottom of Figure 26, the majority of Ontario smart pump adopters (i.e., 10 out of 13) have failed to reap the benefits of smart pumps resulting in negative ROI. This situation could be corrected, if these institutions ensure that (a) the majority of their drug concentrations and dosing units are standardized and that this information is synchronized across all necessary departments (i.e., nursing, medicine, and pharmacy), and (b) they promote a culture of safety around use of the Dose Error Reduction systems and monitor compliance.

Figure 26: Current status of Ontario smart pump adopters in relation to their adherence to “key requisites to successful smart pump implementation”
6.1.3 Current status of Ontario smart pump adopters in relation to their maintenance and monitoring capabilities

Until institutions integrate PPID, the usefulness of the CQI data will be limited as it will lack contextual information needed to fully interpret the data. Figure 27 below illustrates current Ontario smart pump adopters maintenance (i.e., drug library updates) and monitoring (i.e., CQI analysis) capabilities as a function of (1) whether or not institutions have wireless infrastructure, and (2) whether or not hospitals have Positive Patient Identification (PPID). The total number of institutions is 10 rather than 13 as 3 of them either do not have wireless infrastructure or they purchased pumps that do not have wireless abilities. As shown in Figure 27 below, the majority of current Ontario smart pump adopters (i.e., 8 out of 10) do not have wireless capability and do not have PPID. Thus, these 8 institutions cannot readily maintain their drug library and monitor their CQI data. The remaining 2 institutions have wireless infrastructure but do not have PPID. Therefore, these two institutions can frequently update their drug library and download CQI data but their CQI data is of moderate use. That is, although these latter two institutions can readily access the data, it does not contain patient specific data that helps contextualize the information.

<table>
<thead>
<tr>
<th>PPID</th>
<th>Wireless</th>
<th>CQI data: Very useful</th>
<th>CQI data: Limited usefulness</th>
<th>Drug library: Infrequent updates</th>
<th>Drug library: Frequent updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>Limited accessibility</td>
<td>Limited accessibility</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Limited accessibility</td>
<td>Limited accessibility</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Moderate usefulness</td>
<td>Limited accessibility</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Very useful</td>
<td>Very useful</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 27: Current status on Ontario smart pump adopters in relation to their maintenance and monitoring capabilities.
7 Top Five Recommendations when Migrating to Smart Pump Systems

1. Establish standardized concentrations and dosing units prior to smart pump implementation to ensure return on investment.

2. Select a smart pump that is designed to encourage user entry into the Dose Error Reduction System (DERS), and mandate/monitor use of DERS. If not, nurses will bypass the safety features of the pump by programming in the generic mode, thereby leading to a negative ROI.

3. Although presence of a fully built wireless networked environment is not imperative, it is highly recommended as it is necessary for frequent drug library updates and for continuous quality improvement.

4. Institutions must prepare nurses for the cultural shift of having to think in terms of dose rate (e.g., mg/hr) instead of a flow rate (e.g., ml/hr). That is, prior to introduction of infusion pumps, nurses would hang the intravenous (IV) medication bag and count the drip rate (i.e., ml/hr). With the creation of traditional IV pumps, this practice remained as nurses were required to enter the flow rate and volume to be infused. Given that physician orders for continuous infusions are typically provided in dose rate (e.g., mg/hr), nurses would convert the dose rate into a flow rate prior to programming the pump. With smart pumps, however, nurses are provided with the option to enter the flow rate or the dose rate. Institutions should encourage entry of dose rate as it reduces the need for error-prone mathematical conversions.

5. Recognizing that full optimization of smart pumps is dependent on their seamless integration with other systems, including bar coded medication administration (BCMA) and Positive Patient Identification (PPID), institutions should assess how readily BCMA and PPID could be added to their system when selecting a smart pump.
8 References


9 Appendix

9.1 Strategy

9.1.1 Project buy-in and approval

Of the seven current Ontario smart pump users that were asked about the processes used for obtaining project buy-in and approval,

- four hospitals (57%) reported that they provided their senior leadership with education on smart infusion technology;
- one hospital (14%) reported that they had board presentations;
- two hospitals (29%) reported that there was no need for them to get an explicit project buy-in;
- and, two hospitals (29%) reported that the decision to implement a smart infusion system was made by their finance department.

One hospital had done both senior leadership education and board presentations.

![Chart showing hospital responses to project buy-in and approval processes]

9.1.2 Project scope

The Ontario smart pump users that participated in the study were asked whether their project scope included smart infusion systems’ wireless capability, bar-coding feature and ability to interface with other health information systems such as CPOE, PhIS, PPid, or eMAR.

- Seven hospitals considered smart infusion systems’ wireless capability (64%, N = 11)
- Two hospitals considered barcoding feature (22%, N = 9)
- One hospital considered system interfaces (13%, N = 8)
9.1.3 Changes that coincided with smart infusion system implementation

Eleven current Ontario smart pump users reported changes that coincided with their smart infusion system implementation.

- None of the hospitals changed their IV drug labels.
- Three hospitals (27 %) modified their drug order practices.
- One hospital (9 %) implemented a smart infusion system for syringe and epidural pumps at the same time.
- Six hospitals modified their policies and procedures (55 %).

<table>
<thead>
<tr>
<th>Items</th>
<th>Number of Positive Responses</th>
<th>Positive Response Rate</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug labels</td>
<td>0</td>
<td>0%</td>
<td>11</td>
</tr>
<tr>
<td>Drug order practices</td>
<td>3</td>
<td>27%</td>
<td>11</td>
</tr>
<tr>
<td>Implemented other pump types</td>
<td>1</td>
<td>9%</td>
<td>11</td>
</tr>
<tr>
<td>Policies &amp; Procedures</td>
<td>6</td>
<td>55%</td>
<td>11</td>
</tr>
<tr>
<td>Drug order forms</td>
<td>1</td>
<td>9%</td>
<td>11</td>
</tr>
</tbody>
</table>

9.2 Project Management

9.2.1 Formal project manager

Of the 13 Ontario smart pump users, six hospitals (46 %) had a formal project manager for the migration process while seven of the hospitals (54 %) did not.
9.2.2 Initial budget

Nine Ontario smart pump users answered the question about whether their initial budget for migrating to a smart infusion system included the costs associated with future upgrades and maintenance, extra human resources for implementation and maintenance.

- Four (44 %) hospitals budgeted for future upgrades and maintenance.
- Five (56 %) hospitals budgeted for extra human resources for implementation.
- One (11 %) hospital budgeted for extra human resources for maintenance.

<table>
<thead>
<tr>
<th>Questions / Items</th>
<th>Positive Response Rate</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Future upgrades and maintenance</td>
<td>44%</td>
<td>9</td>
</tr>
<tr>
<td>Extra human resources for implementation</td>
<td>56%</td>
<td>9</td>
</tr>
<tr>
<td>Extra human resources for maintenance</td>
<td>11%</td>
<td>9</td>
</tr>
</tbody>
</table>

9.2.3 Most challenging milestones

Thirteen Ontario smart pump users answered the question regarding the most challenging milestones they encountered in their migration to smart infusion systems. The challenges shown below are those that more than one hospital experienced.

1. Developing drug library: 5 hospitals (38 %)
2. Standardizing IV medications: 3 hospitals (23 %)
3. Tight timeline: 3 hospitals (23 %)
4. Training nurses: 2 hospitals (15 %)
5. Having no designated project manager: 2 hospitals (15 %)
6. Getting nurses buy-into using DERS: 2 hospitals (15 %)
9.3 Drug Library

9.3.1 Stakeholders involved in drug library development

Thirteen Ontario hospitals that are currently using a smart infusion system reported which stakeholder groups were involved in their drug library development process. Nursing and pharmacy were involved in the drug library development process at most of the hospitals (100% and 92%, respectively). Other stakeholder groups included medicine, patient/medication safety, biomedical engineering and executive sponsor (listed in decreasing order of frequency).

<table>
<thead>
<tr>
<th>Stakeholder Group</th>
<th>Number of Hospitals</th>
<th>Positive Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>12</td>
<td>92%</td>
</tr>
<tr>
<td>Nursing</td>
<td>13</td>
<td>100%</td>
</tr>
<tr>
<td>Medicine</td>
<td>8</td>
<td>62%</td>
</tr>
<tr>
<td>Biomedical Engineering</td>
<td>1</td>
<td>8%</td>
</tr>
<tr>
<td>Patient/Medication Safety</td>
<td>3</td>
<td>23%</td>
</tr>
<tr>
<td>Vendor</td>
<td>2</td>
<td>15%</td>
</tr>
<tr>
<td>Executive Sponsor</td>
<td>1</td>
<td>8%</td>
</tr>
</tbody>
</table>

9.3.2 Number of drugs in drug library

Nine current smart infusion system adopters reported the approximate number of drugs in their drug library.

- Six hospitals (67%) had more than 100 drugs.
- Two hospitals (22%) had less than 50 drugs.
- One hospital had (11%) had between 51 to 100 drugs.
9.3.3 Resources used for developing drug library

Hospitals that are currently using a smart infusion system were asked about the resources they used for developing their drug library. The most frequently used resources were as follows: current formulary (6 hospitals), followed by sample drug library from vendors (5 hospitals), vendor expertise (2 hospitals), literature (2 hospitals), other hospitals’ drug library (2 hospitals), hospital policies and procedures (2 hospitals) and current IV drug usage statistics (1 hospital).

9.3.4 Drug library contents

Current Ontario smart pump users that participated in the study were asked about the following items related to their drug library.

- Eleven hospitals (92 %, \( N = 12 \)) had a maximum of two to three concentrations per drug.
- Six hospitals (55 %, \( N = 11 \)) had drugs with wildcard concentrations (i.e. concentrations that are manually entered by users).
- Ten hospitals (83 %, \( N = 12 \)) had drugs with hard limits.
- Eleven hospitals (92 %, \( N = 12 \)) had drugs with soft limits.
- Five hospitals (45 %, \( N = 11 \)) used clinical advisories.
• Three hospitals (43 %, \(N = 7\)) used default doses.
• Three hospitals (27 %, \(N = 11\)) had all continuous IV drugs in their drug library.
• Three hospitals (27 %, \(N = 11\)) had all intermittent IV drugs in their drug library.
• Four hospitals (44 %, \(N = 9\)) had all bolus infusions in their drug library.

![Bar chart showing drug library categories]

9.4 Evaluation and Acquisition

9.4.1 RFP

Out of 12 Ontario hospitals that are currently using a smart infusion system, 10 of them (83 %) issued a RFP as a part of their acquisition process. Two hospitals (17 %) did not issue a RFP as they chose to just upgrade their existing non-smart pumps to smart pumps.
9.4.2 Evaluation methods

Vendor presentation, pump and show day, vendors’ reference site visits or interviews and clinical simulations were the primary ways of evaluating different smart infusion system products for the Ontario smart pump users who participated in the study.

- Eight hospitals (80 %, $N = 10$) had vendors come to their site and present their products (i.e. vendor presentation).
- Eleven hospitals (85 %, $N = 13$) had demo systems on their site for the staff to try using the pumps (i.e. pump and show day).
- Seven hospitals (58 %, $N = 12$) visited and/or interviewed vendors’ reference sites.
- Seven hospitals (58 %, $N = 12$) had demonstration systems for users to try.

9.4.3 Key decision making factors

Eleven current smart pump users in Ontario reported the key factors that led them to select the product they implemented. A total of nine different factors were reported by the hospitals. The graph below shows the top four most frequently quoted factors, (functionality, ease of use, nurse preference and prior vendor relationship), that drove the hospitals’ product selection process.
9.5 Pump training

9.5.1 Methods for training nurses

Eleven current smart pump users in Ontario reported on the methods they used for training nurses on the use of smart infusion pumps. The most frequently used methods were classes (100%), followed by super users (91%), tip sheets on pumps (27%), computer based modules (18%) and practice pumps on units (18%) (listed in decreasing order of frequency).
9.5.2 Training provider

Eleven current smart pump users in Ontario answered the question related to who provided training to their nurses on using smart infusion pumps. For all hospitals, vendors led their training classes in collaboration with super users (73%) and nurse educators (55%).

9.5.3 Training class organization

Most of the pump training classes for nurses were organized in small groups with hands-on learning (78%, N = 9). At one hospital (11%, N = 9), the training class was of a lecture style and took place in a large classroom. Finally, at another hospital (11%, N = 9), the training was given on an individual basis with hands-on learning (i.e. each nurse was given a pump).

9.5.4 Timing of training classes

Most of the current smart pump users in Ontario held their nurse training classes one week or days before the go-live date (71%, N = 7). At one hospital (14%, N = 7) the training classes were offered two to three weeks prior to the go-live date. Finally, at
another hospital (14 %, \(N = 7\)), the training classes were offered one month prior to the go-live date.

9.5.5 Staff recruitment method for training classes

Ten Ontario smart pump users reported on the methods they used for recruiting their nurses to attend pump training classes. Most of the hospitals (9 hospitals) made it mandatory for the staff to attend the training classes, and four of them allocated time to relieve staff. One hospital had rounds and pulled the staff from the floor to participate in the training.

9.6 Support & Maintenance

9.6.1 Update training

Nine current Ontario smart pump users reported on whether or not any update training had been provided after implementing smart pumps.

- Five (56 %) hospitals had not provided any update training.
- Three (33 %) hospitals had provided ad-hoc training.
- One (11 %) hospital had received CQI training from the vendor.
9.6.2 Stakeholder groups responsible for uploading drug library updates

For the majority of current Ontario smart pump users (five hospitals, 56%, N = 7), biomedical engineering was responsible for uploading drug library updates to the pumps. For two of the hospitals, nursing was responsible for the task, and for the remaining hospital, IT was responsible.

9.6.3 Time required for uploading drug library updates

Nine Ontario smart pump users reported on the time taken to upload a drug library update to all of their smart pumps. For three (33.5%) hospitals that are using wireless pumps, it takes them less than an hour. For another three (33.5%) hospitals, it takes two to five days. For two hospitals, it takes them 6 days or longer. Finally, for a small hospital without a wireless infrastructure, it takes one day to upload drug library updates to all the pumps.
9.6.4 Frequency of drug library update

Fourteen current Ontario smart pump users reported the frequency of their drug library updates. Four hospitals had never updated their drug library since implementing their pumps. Four hospitals update their drug library when there is a pump maintenance or a major product upgrade/update. One hospital updates its drug library on an ad-hoc basis. Only five hospitals (35 %) update their drug library on a regular basis at least every six months.

9.6.5 Downloading and compiling CQI data

Seven current Ontario smart pump users reported on which stakeholder groups are responsible for downloading and compiling CQI data from their smart pumps. For four hospitals, biomedical engineering was responsible for this task. For two of these hospitals, biomedical engineering collaborated with nursing or IT. For the remaining two hospitals, nursing was responsible for this task.
9.6.6 Training for analysis of CQI data

Eight current Ontario smart pump users reported whether or not they had received training for analyzing CQI data from their vendor, and if so, when they received their training. The majority of the hospitals (six hospitals, 75%) never received CQI data analysis training. Only one of the hospitals (13%) received training prior to implementing their smart pumps, and the remaining hospital (13%) received training more than a year after implementing their smart pumps.